



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

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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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to define a single-serving container; require dual-column labeling for certain containers; update, modify, and establish several reference amounts customarily consumed (RACCs); amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations. We are taking this action to provide consumers with more accurate and up-to-date information on serving sizes.

DATES: Effective date: The final rule becomes effective on July 26, 2016.

Compliance date: The compliance date of this final rule is July 26, 2018, for manufacturers with \$10 million or more in annual food sales, and July 26, 2019, for manufacturers with less than \$10 million in annual food sales. See Section IV, Effective and Compliance Dates, for more detail.

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I. Executive Summary

A. Purpose of the Final Rule

Following the passage of the Nutrition Labeling and Education Act (NLEA) of 1990 (Pub. L. 101-535), which added section 403(q) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(q)), we issued various regulations related to serving size requirements (see 21 CFR 101.9 and 101.12). Since we established those regulations, there have been developments that have compelled us to reevaluate our regulations on serving sizes and determine whether and what, if any, revisions are needed to ensure that the Nutrition Facts label meets its intended goal of providing consumers information to assist them in maintaining healthy dietary practices. Specifically, such developments include the availability of newer consumption data, research showing that amounts of food consumed by the American public have changed, and the availability of recent consumer research on the use and understanding of the Nutrition Facts label.

In consideration of these new developments, this rule amends our regulations in §§ 101.9 and 101.12. Resulting from our evaluation of the new consumption data, this rule amends the RACCs that are used to determine serving sizes consistent 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. Additionally, in consideration of recent consumption data, research on consumption, and research on consumer understanding of the Nutrition Facts label, this rule amends some of the required procedures used to determine serving sizes, amends the definition of a single-serving container, and requires that certain containers of foods bear an additional column of nutrition information to help consumers understand the nutritional significance of consuming an entire container of certain foods containing multiple servings. Overall, the changes finalized in this rule are designed to ensure that serving sizes are based on current consumption data and to provide consumers with information on the Nutrition Facts label related to the serving size that will assist them in maintaining healthy dietary practices.

B. Summary of the Legal Authority

The NLEA amended the FD&C Act to provide FDA with the authority to require nutrition labeling on most packaged foods we regulate. Specifically, section 403(q)(1)(A)(i) of the FD&C Act requires, with certain exceptions, that food that is intended for human consumption and offered for sale bear nutrition information that provides a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure that is appropriate to the food, and is our primary legal authority to issue the regulations in this final rule. Section 2(b)(1)(B) of the NLEA further requires the Secretary of Health and Human Services to issue regulations “which establish standards...to define serving size.” Additionally, we are relying on section 2(b)(1)(A) of the NLEA, which states that requirements

in regulations issued under the authority of the NLEA, including serving size requirements, shall be “conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” Finally, we are relying on the authorities in sections 701(a), 403(a)(1), and 201(n) of the FD&C Act (21 U.S.C. 371(a), 343(a)(1), and 321(n)) for amendments in this final rule. Under section 701(a) of the FD&C Act, we have authority to issue regulations for the efficient enforcement of the FD&C Act. Under section 403(a) of the FD&C Act, a food is deemed misbranded if its labeling is false or misleading in any particular. Additionally, under section 201(n) of the FD&C Act, in determining whether or not a food is misbranded because its labeling is misleading, we must take into account not only representations made or suggested, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to consequences that may result from the use of the food. All of the authorities listed in this paragraph give us the authority to issue this final rule related to serving size labeling.

C. Summary of the Major Provisions of the Final Rule

1. Single-Serving Containers and Dual-Column Labeling

Over the last 20 years, evidence has accumulated demonstrating that container and unit sizes can influence the amount of food consumed. For containers and units of certain sizes, consumers are likely to eat the entire container or unit in one sitting. For other container and unit sizes, consumers may consume the container or unit in one sitting or may consume the container or unit over multiple sittings or share the container or unit contents with other consumers. To address containers that may be consumed in a single-eating occasion, we are requiring that all containers, including containers of products with “large” RACCs (i.e., products with RACCs of

at least 100 grams (g) or 100 milliliters (mL)), containing less than 200 percent of the RACC be labeled as a single-serving container. To address containers and units that may be consumed in one or more sittings, or shared, we are requiring that containers and units that contain at least 200 percent and up to and including 300 percent of the RACC be labeled with a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the entire container, in addition to the required column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (i.e., the serving size derived from the RACC).

2. Changing the RACCs

We established RACCs in 1993 based, in part, on data from Nationwide Food Consumption Surveys (1977-1978 and 1987-1988) conducted by the U.S. Department of Agriculture (USDA). Over the last decade, there has been general recognition that consumption patterns have changed. To determine changes in serving sizes and whether the RACCs should be updated, we analyzed recent food consumption data from the 2003-2008 National Health and Nutrition Examination Surveys (NHANES) (hereinafter referred to as the NHANES 2003-2008 surveys or NHANES 2003-2008 consumption data, as applicable). Generally, this rule amends RACCs if the NHANES median consumption data have increased or decreased by at least 25 percent compared to the 1993 RACCs. However, consistent with our regulations in § 101.12(a), we have considered other factors, such as designating the same RACCs for products with similar consumption data and similar dietary usage or product characteristics.

In addition, since the final rule on serving sizes published in 1993, we have received requests from manufacturers to modify, establish, and identify appropriate product categories

within the tables in § 101.12(b) and change the serving size for various food products. Using the data currently available to us, we are also addressing these requests in this final rule.

D. Technical Amendments

We have been alerted to a number of technical amendments that should be made to the serving size regulations in §§ 101.9 and 101.12. This final rule includes a number of technical amendments to help clarify the serving size requirements in these regulations.

E. Effective and Compliance Dates

We are establishing a compliance date of 2 years after the final rule's effective date for manufacturers with \$10 million or more in annual food sales, and 3 years after the final rule's effective date for manufacturers with less than \$10 million in annual food sales. (For more details, see Section IV, Effective and Compliance Dates.)

F. Costs and Benefits

We have developed one final regulatory impact analysis (FRIA) for this final rule as well as the final rule entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (the Nutrition Facts final rule). The FRIA discusses key inputs in the estimation of costs and benefits of the changes finalized by the rules and assesses the sensitivity of cost and benefit totals to those inputs. The two nutrition labeling rules--which have a compliance date of 2 years after the final rule's effective date for manufacturers with \$10 million or more in annual food sales, and 3 years after the final rule's effective date for manufacturers with less than \$10 million in annual food sales--have impacts, including the sign on net benefits, that are characterized by substantial uncertainty. The primary sensitivity analysis shows benefits having the potential to range

between \$0.2 and \$2 or \$5 billion, and costs ranging between \$0.2, \$0.5 and \$0.8 billion (annualized over the next 20 years, in 2014 dollars, at seven percent interest).¹

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

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

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

II. Background

A. Serving Size Proposed Rule

In the Federal Register of March 3, 2014 (79 FR 11989), we published a proposed rule (the serving size proposed rule or the proposed rule) to amend our serving size regulations, in part, in response to recommendations of the Report of the Working Group on Obesity, “Calories Count,” March 12, 2004 (Ref. 1), and our recognition that portion sizes have changed since we first published serving size regulations in 1993 (1993 serving size final rule, 58 FR 2229, January 6, 1993). We also published technical amendments to the 1993 serving size final rule on August 18, 1993 (58 FR 44039). The proposed rule also discussed six citizen petitions. The intended effect of the proposed rule, when finalized, was to provide consumers with more accurate and up-to-date information on serving sizes. In brief, the proposed rule would:

¹ There is substantial uncertainty regarding the impacts of the two nutrition labeling rules. For a full discussion of the uncertainty, please see the Welfare Estimates – Primary Sensitivity Analysis section of the Regulatory Impact Analysis.

- Amend the definition of a single-serving container to remove the exception for products with large RACCs. Preexisting § 101.9(b)(6), which this rule will replace upon the effective date, required that a product that is packaged and sold individually that contains less than 200 percent of the applicable RACC be considered to be a single-serving container, and that the entire content of the product be labeled as one serving, unless the product contains more than 150 but less than 200 percent of the RACC and has an RACC of 100 g or 100 mL or larger. Under the preexisting regulation, manufacturers of products that contain more than 150 but less than 200 percent of the RACC and have an RACC of 100 g or 100 mL or larger (large-RACC products) are permitted to label the product as containing 1 or 2 servings, at the manufacturer's discretion (§ 101.9(b)(6)). The proposed rule would remove the exception for large-RACC products being labeled as one or two servings so that all products packaged and sold individually and that contain less than 200 percent of the RACC would be required to be labeled as a single-serving container.
- Require an additional column within the Nutrition Facts label to list the quantitative amounts and percent DVs for the entire container, to the right of the preexisting column listing the quantitative amounts and percent DVs for a serving that is less than the entire container (i.e., the serving size derived from the RACC), for products that are packaged and sold individually and contain at least 200 percent and up to and including 400 percent of the applicable RACC.
- Update the RACCs when there is a significant change between the median amount consumed from 2003-2008 NHANES consumption data and the RACCs established in the 1993 serving size final rule.

- Modify and establish RACCs for certain product categories based on manufacturer requests and our initiative.
- Amend the serving size for breath mints.
- Make technical amendments to various aspects of the serving size regulations.

We provided an opportunity to comment on the serving size proposed rule until June 2, 2014. On May 27, 2014, we extended the comment period until August 1, 2014 (79 FR 30056). We received more than 500 comments in response to the proposed rule. Most submissions came from individuals. We also received comments from industry and trade associations, consumer and advocacy groups, academic organizations, State governments, and foreign government agencies.

B. Legal Authority

Our primary legal authority to issue regulations that establish requirements for serving size is derived from section 403(q) of the FD&C Act. Specifically, section 403(q)(1)(A)(i) of the FD&C Act requires, with certain exceptions, that food that is intended for human consumption and offered for sale bear nutrition information that provides a serving size that reflects the amount of food customarily consumed and is expressed in a common household measure that is appropriate to the food.

The NLEA added section 403(q)(1)(A)(i) to the FD&C Act and, under section 2(b)(1)(B) of NLEA, required that we issue regulations that establish standards to define serving size. We established those standards in the 1993 serving size final rule, and we have determined that amendments to those regulations are needed. We have analyzed consumption data for various food products and have determined that the data warrant amending many of the RACCs established in 1993. Additionally, both on our own initiative and in response to various requests,

we have analyzed data for products that are not listed in the tables in § 101.12(b), and are establishing additional RACCs. Thus, in accordance with section 403(q)(1)(A)(i) of the FD&C Act, we are amending the RACCs in § 101.12(b) to reflect the current amounts customarily consumed for products already listed in § 101.12(b), as well as products not listed in § 101.12(b). Additionally, under the same authority we are amending related regulations in §§ 101.9 and 101.12 that set forth procedures for determining serving sizes for use on product labels based on the reference amounts. Included among these amendments are revisions to the procedures for determining what products must be labeled as a single serving.

Further, in addition to requiring FDA to issue regulations that establish standards to define serving size, section 2(b)(1)(A) of the NLEA states that the regulations shall require such information to be “conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” Under this authority, we are amending § 101.9 to require that certain products provide an additional column within the Nutrition Facts label that lists the quantitative amounts of the required nutrients and food components, and percent DVs for such nutrients and food components, for the entire container or unit of food as well as the column listing the quantitative amounts and percent DVs for a serving of food that is less than the entire container or unit. Section 2(b)(1)(A) of the NLEA provides authority for this amendment because the additional column of information will help consumers to understand the nutritional significance of consuming an entire container or unit of certain foods containing multiple servings in the context of a total daily diet. As discussed further in section III.C.1., research has shown that package and portion size play a role in influencing the amounts that consumers eat, and that consumers can be confused about the amount of nutrients they consume in packages

containing more than one serving but that could be consumed in a single eating occasion. The amendment is intended to help consumers understand the amounts of nutrients in certain containers and units of food, as well as the DVs for those nutrients, so that those amounts can be taken into consideration when evaluating a daily diet.

Other relevant authorities that we are relying on for the amendments in this rule include sections 701(a), 403(a)(1), and 201(n) of the FD&C Act. Under section 701(a) of the FD&C Act, we have authority to issue regulations for the efficient enforcement of the FD&C Act. We may issue regulations for the efficient enforcement of the FD&C Act in order to “effectuate a congressional objective expressed elsewhere in the Act” (Association of American Physicians and Surgeons, Inc. v. FDA, 226 F. Supp. 2d 204, 213 (D.D.C. 2002) (citing Pharm. Mfrs. Ass’n. v. FDA, 484 F. Sup. 1179, 1183 (D. Del. 1980))). Under section 403(a) of the FD&C Act, a food is deemed misbranded if its labeling is false or misleading in any particular. Additionally, under section 201(n) of the FD&C Act, in determining whether or not a food is misbranded because its labeling is misleading, we must take into account not only representations made or suggested, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to consequences that may result from the use of the food. These other authorities, in addition to the authorities described previously in this document, give us the authority to issue this final rule related to serving size labeling.

III. Comments and FDA’s Responses

This section discusses the issues raised in the comments on the proposed rule and describes the final rule. For ease of reading, we preface each comment discussion with a numbered “Comment” and each response by a corresponding numbered “Response.” We have numbered each comment to help distinguish among different topics. The number assigned is for

organizational purposes only and does not signify the comment's value, importance, or the order in which it was received.

A. General Comments

(Comment 1) Many comments stated that the labeled serving size represents a recommended amount of food to consume. Other comments stated that we were changing the RACCs from a recommended amount of food to eat to the amount of food that people actually eat. Some comments that thought we were changing the serving size from a recommended amount of food to eat to an amount of food that is customarily consumed supported the change. Some of these comments stated that basing the serving size on the actual amount eaten would make it easier for consumers to understand how many calories and other nutrients they are consuming.

In contrast, other comments asserting that we were changing the serving size from a recommended amount to an amount of food that is customarily consumed opposed the perceived change because, according to those comments, such changes would make it more difficult to use the labeled serving size for diet planning or other dietary practices. Further comments stated that updating the serving size portion of the Nutrition Facts label would increase consumer confusion and encourage excess consumption among those who think that the serving size is based on a recommended amount.

(Response 1) Some of these comments reflect a misunderstanding of the definition of serving size. Under section 403(q)(1)(A)(i) of the FD&C Act, serving size is an amount of food customarily consumed and which is expressed in a common household measure appropriate to the food. Thus, the serving size is not a recommended amount of food to eat and was not described as such in the 1993 serving size final rule.

We acknowledge that some consumers may misconstrue the meaning of the serving size set forth in the FD&C Act. Since the publication of the proposed rule, several studies have been conducted that indicate that some consumers believe serving size specifies a recommended amount of food to eat (Refs. 2, 3, and 4), and we recognize that that such an understanding could lead to increased levels of consumption. In order to help consumers understand issues relating to this final rule, as discussed further in response to comment 2, we intend to conduct nutrition education to help clarify the meaning of the serving size and RACCs.

With regard to the comments that stated that updates to serving sizes would make it difficult to use the serving size for diet planning or other dietary practices, we disagree. Providing the nutrition content of the food based on current consumption amounts informs consumers of the amount of nutrients they are likely to ingest.

(Comment 2) Several comments recommended that we conduct extensive consumer education on the changes in this final rule. Some comments requested that we conduct consumer education in conjunction with the USDA regarding all proposed changes to the Nutrition Facts label and the underlying calculations used to determine the quantities presented on the labels. Several comments asserted that without public education, consumers may not fully understand how to use the Nutrition Facts label so that they can maintain healthy dietary practices.

(Response 2) We agree that an extensive consumer education campaign will serve an important role in continuing to provide information to assist consumers in maintaining healthy dietary practices. Currently, we have available a collection of various educational materials (e.g., videos and an array of other education materials (in English and other languages)) on numerous nutrition topics, including materials on the Nutrition Facts label (e.g., Read the Label, Make Your Calories Count, Using the Nutrition Facts Label) (Ref. 5). These materials are

intended for educators, teachers, health professionals (e.g., dietitians, nutritionists), as well as for consumers. Our intent is to update our existing educational materials and create new educational opportunities to explain the overall role of using the label to assist consumers in maintaining healthy dietary practices, with an emphasis on each of the new changes of the label.

We intend to continue to work in collaboration, and create new partnership opportunities, with other Federal government agencies including other parts of the Department of Health and Human Services, USDA, State health departments, health professional organizations, food manufacturers, retailers, and non-profit organizations that have an interest and responsibilities in nutrition education and health promotion. These partnerships will help us to develop and disseminate our educational materials, which will ease the transition to the revised nutrition label and help consumers to use the label to make informed dietary choices. Through our collaboration with both government and non-government entities, our continued goal is to increase consumers' knowledge and effective use of the new food label, and to ensure that consumers have accurate and adequate resource materials and information to assist them in maintaining healthy dietary practices. Furthermore, we intend to continue with a variety of activities, such as conducting and reporting on existing and planned food labeling research, developing education initiatives at the national and local level, holding regularly scheduled meetings to build labeling education exchanges, and integrating food labeling education into the existing programs (e.g., USDA school-based nutrition education programs). We plan to continue to build partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low-literacy consumers, those with lower incomes, minorities and various specific subpopulations (e.g., children, older adults, women of childbearing age), as well as to the public at large.

(Comment 3) Several comments requested we require that a footnote be added to the Nutrition Facts label to indicate that the serving size is based on typically consumed, not recommended, servings. The comments stated that the purpose of adding this footnote would be to serve as nutrition education to make consumers aware of the true meaning of the labeled serving size.

(Response 3) We recognize the importance of providing consumers with more in-depth information about the meaning of the serving size and, as explained in response to comment 2, intend to make this a key component of our future nutrition education efforts for consumers. At this time, however, we decline to establish as part of this rulemaking a requirement to add a footnote to the Nutrition Facts label that would indicate that the serving size is based on what is typically consumed, rather than what is recommended. We would like to consider this issue further before finalizing a provision that would mandate or voluntarily permit the addition of such a footnote to the Nutrition Facts label. We also note that, while no such footnote as requested in this comment can be added to the Nutrition Facts label voluntarily, manufacturers can voluntarily include a truthful and not misleading statement explaining the meaning of serving size elsewhere on the product label.

(Comment 4) Some comments requested that we change the term “serving size” to prevent consumers from assuming that the serving sizes are recommended servings. Some terms that the comments suggested we use instead were “typical serving,” “unit,” or “quantity.” Another suggestion was to remove the two lines that mention “serving” and add, next to the words “Amount per __,” the fraction of the container that the RACC represents (for example, “Amount per $\frac{2}{3}$ cup ($\frac{1}{8}$ of container)”).

(Response 4) We decline to revise or remove the terms “serving” and “serving size” as suggested by the comments. Section 403(q)(1)(A) of the FD&C Act deems food, unless subject to an exception, to be misbranded unless its label or labeling bears the “serving size.” Therefore, we will continue to require that the terms “serving” and “serving size” be used on product labels.

(Comment 5) Some comments stated that the “serving size” should be expressed in household measurements or that serving size of similar food products should be based off of the same amount of food.

(Response 5) We agree. Section 403(q)(1)(A) of the FD&C Act requires that the serving size be expressed in a common household measure that is appropriate to the food or, if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food. In addition, § 101.12(a)(9) states that products that have similar dietary usage, product characteristics, and customarily consumed amounts should have a uniform reference amount. Section 101.12(a)(9) is not being changed in this final rule and was used as part of the decision making when determining what RACCs to update, modify, and establish in the proposed rule and this final rule.

(Comment 6) Several comments indicated that we should consider a uniform serving size for all food products as is done in some other countries, such as 1 cup or 100 g. The comments stated that having a uniform serving size would allow consumers to be able to make side-by-side comparisons of all products in the grocery store.

(Response 6) We do not agree that a uniform serving size should be used for all foods. Under section 403(q)(1)(A) of the FD&C Act, serving size is defined as the amount of food customarily consumed. As all foods are not customarily consumed in the same amount, establishing a uniform serving size for all foods would not meet this statutory requirement.

B. Single-Serving Containers

Preexisting § 101.9(b)(6) requires that a product that is packaged and sold individually and that contains less than 200 percent of the applicable RACC be labeled as a single serving. This provision, however, does not apply to products that have “large” RACCs (i.e., products that have reference amounts of 100 g (or mL) or larger). Under preexisting § 101.9(b)(6), manufacturers of large-RACC products could decide whether a package that contains more than 150 percent but less than 200 percent of the applicable RACC is 1 or 2 servings (§ 101.9(b)(6)). We provided the exception for large-RACC products based on consumption data available at the time the 1993 rule was issued that showed that “[i]t was much less likely that a person will consume approximately twice the reference amount of a food with a reference amount of 100 g (or mL) or more, than it is that he or she would consume twice the reference amount of a food with a smaller reference amount” (79 FR 11989 at 12000).

In the preamble to the proposed rule (79 FR 11989 at 12001), we discussed the correlation between the consumption variation and the RACCs for all products containing less than 200 percent of the applicable RACC, including products with large RACCs and products that have RACCs that are less than 100 g (or mL), using combined consumption data from the NHANES 2003-2008 surveys (Refs. 6, 7, and 8). The consumption variation is calculated as the standard deviation of the median consumption amount divided by the median consumption amount and then multiplied by 100 to express the figure as the percent variation from the median consumption amount (Ref. 9). The result shows that the correlation coefficient is 0.13, which means that there is a low correlation between the RACCs and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is large. In other words, it is not less likely that a person would consume approximately twice the

reference amount of a food with a reference amount of 100 g (or mL) or more than it is that he or she would consume approximately twice the reference amount of a food with a smaller reference amount. Therefore, in the preamble to the proposed rule we proposed to remove the exemption from the requirement to label a product with a large RACC containing between 150 percent and 200 percent of the applicable RACC as a single-serving container because the exemption is no longer supported by consumption data (79 FR 11889 at 12001).

Additionally, as noted in the preamble to the proposed rule, raising the required cutoff for labeling a product with a large RACC as a single serving may help consumers to more accurately interpret the nutrient amounts in these products (79 FR 11889 at 12001). Research shows that package and portion sizes tend to have a considerable impact on the amount of food consumed (Refs. 10 and 11). Taking into account this research, we stated in the proposed rule that removing the exemption from the requirement to label a product with a large RACC as a single-serving container may help consumers to correctly interpret the nutrient amounts in the food that they are consuming (79 FR 11989 at 12001). In light of this research and the previously discussed analysis on consumption variation, we proposed to remove the large-RACC exemption for single-serving containers.

We also proposed to remove the text in preexisting § 101.9(b)(2)(i)(D), which states that if a unit weighs 200 percent or more of the RACC, the manufacturer may declare one unit as the serving size if the entire unit can reasonably be consumed in one eating occasion, and replace the text with the text in proposed § 101.9(b)(2)(i)(D) (which is discussed in section III.C.).

1. Definition of a Single-Serving Container

(Comment 7) Some comments supported our proposed changes to the definition of a single-serving container. The comments said that labeling foods that are less than 200 percent of

the RACC as a single serving would increase consumer understanding of the nutritional content of foods. Some comments also stated that the proposed changes would provide consistency across all food products on the amount that constitutes a single serving. Other comments provided research in support of our proposed changes to the definition of a single-serving container.

(Response 7) The research provided in the comments is the same as the research discussed in the preamble of the proposed rule (79 FR 11989 at 11998). Lando & Labiner-Wolfe (2007) found that many focus group study participants believed that products like a large muffin or a 20 ounce (oz) soda that contain more than one serving, but are often eaten at a single eating occasion, should be labeled as a single serving (Ref. 12). Other studies have shown that some consumers may tend to experience a “unit bias” and view intact units/packages of food as a marker of the appropriate amount of food to consume (Ref. 13).

(Comment 8) One comment asked that we raise the cutoff for a single-serving container to include containers with up to 300 percent of the RACC. The comment stated that our proposed amendment for single-serving containers to include anything less than 200 percent of the RACC excludes many foods that can reasonably be consumed by one person in a single eating occasion and that food companies could avoid “per package” labeling by simply increasing the container size to slightly more than 200 percent of the RACC.

(Response 8) While we understand the concern that keeping the cutoff for single-serving containers at less than 200 percent may exclude some food products that can reasonably be consumed by one person in a single eating occasion, we decline to increase the definition of a single-serving container to include products containing up to 300 percent of the RACC. Under section 403(q)(1)(A)(i) of the FD&C Act, serving size means the amount customarily consumed.

The RACCs we have established are reference amounts of food that are customarily consumed per eating occasion. As such, we do not consider it appropriate to label foods containing 200 percent or more of the applicable RACC as single-serving containers because that would be at least twice the amount we have determined is customarily consumed. However, we agree with these comments that such products may reasonably be consumed by one person in a single eating occasion, and as discussed in section III.B., full-package nutrition information, or per-unit nutrition information, as applicable, for products containing at least 200 percent and up to and including 300 percent of the RACC will be required for certain products through dual-column labeling.

(Comment 9) One comment requested clarification on the meaning of the phrase “products that are packaged and sold individually.” The comment noted that it understood the phrase “products that are packaged and sold individually” to mean products that consist of a single unit and to exclude products that are divided into discrete units. The comment stated that if the phrase “products that are packaged and sold individually” does include products that are divided in discrete units, every product would be a product that is “packaged and sold individually.” Accordingly, the comment questioned whether the proposed single-serving and dual-column labeling requirements would apply only to products that consist of a single unit, or whether the requirements would also apply to non-discrete bulk products and products divided into discrete units. The comment also requested clarification on whether a product that is “packaged and sold individually” must be considered a single-serving container if it contains less than 200 percent of the RACC, and whether it must provide dual-column labeling if it contains 200 percent to 400 percent of the RACC.

(Response 9) In proposed § 101.9(b)(6) we use the phrase “products that are packaged and sold individually” and weighing less than 200 percent of the RACC to describe products for which single-serving container labeling requirements would apply. The phrase “products that are packaged and sold individually” was also used in the serving size proposed rule to describe products for which the proposed dual-column labeling requirements would apply, provided that they contained at least 200 and up to and including 400 percent of the RACC. In both of these cases we are using the phrase “products that are packaged and sold individually” to describe any package bearing a Nutrition Facts label.

A product that is packaged and sold individually, i.e., a container that bears a Nutrition Facts panel, is considered a single-serving container if it contains less than 200 percent of the RACC. A product that is packaged and sold individually would be required to provide dual-column labeling if it contains at least 200 percent and up to and including 300 percent of the RACC, unless an exception from the requirement applies. The change from 400 percent of the RACC as the upper limit for the dual-column labeling requirements to 300 percent of the RACC as the upper limit for the dual-column labeling requirements is discussed in section III.B. While § 101.9(b)(2)(i) provides requirements for the serving size declaration for multiserving products in discrete units, products that satisfy the requirements of § 101.9(b)(6) (i.e., products that are packaged and sold individually and that contain less than 200 percent of the applicable reference amount) are excepted from § 101.9(b)(2) (see 58 FR 2229 at 2234). There was no proposal to change this provision in the proposed rule, and it has not been amended in this final rule. Therefore, products in discrete units that are packaged and sold individually and that contain less than 200 percent of the applicable reference amount are required to be labeled as a single serving under § 101.9(b)(6). Products that contain discrete units and in which each discrete unit weighs

at least 200 percent and up to and including 300 percent of the reference amount are required under § 101.9(b)(2)(i)(D) to bear two columns listing the quantitative amounts and percent DVs: One providing nutrition information for a serving that is less than the unit (i.e., the serving size derived from the reference amount) and one providing nutrition information for the entire unit. Further, products in discrete units that are packaged and sold individually and contain at least 200 percent and up to and including 300 percent of the reference amount are required to comply with the dual-column labeling requirements in § 101.9(b)(12)(i). Similarly, products not in discrete units that are packaged and sold individually and contain at least 200 percent and up to and including 300 percent of the reference amount are required to satisfy the dual-column labeling requirements in § 101.9(b)(12)(i).

(Comment 10) Several comments pertained to multiple individually wrapped units in a single container, for which the combined weight of the units in the larger package is less than 200 percent of the RACC. The comments stated that products containing individual units in a container where the entire container weighs less than 200 percent of the RACC are unlikely to be consumed in a single eating occasion. One comment requested an exemption from the single-serving container requirement in a scenario in which a package weighing less than 200 percent of the RACC contains two discrete stuffed sandwiches, and requested that each sandwich, rather than the entire package, be considered one serving. The comment stated that under the proposed amendments to the definition of a single-serving container, the entire package containing the two stuffed sandwiches would need to be labeled as one serving. The comment stated that labeling each discrete stuffed sandwich as a single serving would be consistent with how consumers use and eat these types of products and asserted that consumers typically eat one individually wrapped unit in a single eating occasion, rather than opening a second unit. Another comment

requested that we provide an exemption generally from the definition of single-serving container where a package contains multiple individually wrapped units, and each individual unit is labeled as a serving.

(Response 10) We disagree with comments suggesting that products containing discrete units in a container that weighs less than 200 percent of the RACC should be exempt from the single-serving container requirements, regardless of whether the individual units in the container are wrapped. Products containing discrete units in a container weighing less than 200 percent of the RACC were required to be labeled as a single-serving container under the 1993 requirements, unless the product qualified for the large-RACC exception discussed in section III.B. We did not propose to change this requirement in the proposed rule and are not changing it in the final rule. Other provisions of our regulations permit additional flexibility with respect to how products in discrete units are labeled. As explained in response to comment 12 and as reflected in § 101.9(b)(6), for products that are packaged and sold individually (i.e., products bearing a Nutrition Facts panel) that contain more than 150 percent and less than 200 percent of the applicable reference amount, manufacturers may voluntarily add a second column of nutrition information to the left of the column that provides nutrition information per container that will provide nutrition information per common household measure that most closely approximates the reference amount. This would allow manufacturers of products that are packaged and sold individually and that contain two discrete units weighing more than 75 percent and less than 100 percent of the reference amount to voluntarily provide a second column that provides nutrition information per unit. Additionally, for packages that weigh less than 200 percent of the RACC each and that are contained within a larger outer container, manufacturers have the option of labeling each individual package with a Nutrition Facts panel that states that the individual

package or container is one serving, and then labeling the outer container to state the number of servings as the number of individual packages within the outer container (§ 101.9(b)(8)(iv)). Finally, in order to provide additional flexibility to manufacturers that want to list nutrition information per unit of food, this final rule amends § 101.9(b)(10)(ii), which allows manufacturers to provide an additional column of nutrition information “[p]er one unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit.” This final rule removes language in § 101.9(b)(10)(ii) limiting the provision to use only with multiserving containers. These amendments will allow single-serving products to voluntarily provide an additional column of nutrition information per unit of a product that is in discrete units.

2. Single-Serving Container Option for Large-RACC Products

(Comment 11) Several comments said that our analysis of the correlation between the consumption variation and the RACCs for all products containing less than 200 percent of the applicable RACC is flawed. The comments stated that we defined the average variability in the analysis as the standard deviation as a percent of the mean and that this represents the standard deviation of individual intakes from one person to the next. The comments stated that the standard deviations of the medians in all tables in our analysis are actually the standard errors of the medians and not the standard deviations of individual intakes as previously described (Ref. 9). The comments stated that because we did not actually conduct the appropriate analysis, no conclusion should be drawn from these reported summaries.

(Response 11) After carefully reexamining the data described in the Memorandum-to-file dated February 11, 2014 (Ref. 9), we agree that the standard deviations of the median are, in fact,

the standard errors of the medians. Therefore, we have revised the correlation between the consumption variation and the RACCs for all products.

We disagree, however, that no conclusion should be drawn because of the error. The revised correlation coefficient, after adjusting the standard errors to standard deviations by multiplying with square roots of the sample size, is reduced to 0.13 from 0.18. This means that there is an even lower correlation between the RACCs (whether the reference amount is more than or less than 100 g or mL) and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is “large.” In other words, the correct calculation reinforces the conclusion that it is not less likely that a person would consume approximately twice the reference amount of a food with a reference amount of 100 g (or mL) or more than it is that he or she would consume approximately twice the reference amount of a food with a smaller reference amount.

(Comment 12) One comment expressed concern about the impact that removing the exception for large-RACC products in § 101.9(b)(6) would have on products with varying densities. According to the comment, some varieties of the same type of product have serving sizes that are less than 200 percent of the RACC, while other varieties of the same type of product have serving sizes that are 200 percent of the RACC or greater. The comment noted as an example canned soups of different varieties that are often packaged in the same size and type of container, for which the different varieties may have different densities (e.g., a cream-based soup may be heavier than a broth-based soup). According to the comment, under the proposed rule soups containing less than 200 percent of the RACC, or less than 490 g, would be required to be labeled as a single serving, while soups containing 200 to 400 percent of the RACC, or 490 to 980 g, would be labeled with dual-column labeling.

Another comment noted that inconsistencies in nutrition label formats could result from the use of single- and dual-column labeling for similar products which could lead to consumer confusion and make it difficult for consumers to compare identical products that may contain 200 percent or more of the RACC and use a dual-column label with single-serving container products that use a single-column label (e.g., 19 oz, 24 oz, and 40 oz products of identical formulation). The comment said that these products are often merchandised side-by-side in supermarkets and asserted that the presence of two different serving sizes and two different formats (dual-column labeling for the 19 and 24 oz product versus single-column labeling for 13 and 15 oz products) would confuse the consumer.

We also received a comment requesting that we allow voluntary dual-column labeling for products that contain more than 150 and less than 200 percent of the RACC to present nutrition information per serving and per common household measure closest to the RACC. The comment noted that under the proposed rule, such products would be single-serving containers and would be required to declare nutrition information on a “per container” basis (proposed § 101.9(b)(6)). The comment asserted that it would be appropriate to provide nutrition information on a “per container” basis for these products but noted that some consumers may not eat the entire container in one sitting. The comment suggested that some consumers would find it helpful to have nutrition information on the label for an amount of food that approximates or is closest to the RACC.

One comment noted that it is a common practice for retailers to create a private label product with a “slightly lower” net content. In these instances, consumers would compare a brand name product to a private label product with a slightly lower net content and think the private label brand has a better nutritional profile than the brand name. The comment stated that

this is because consumers would fail to understand that the nutritional difference is a result of the difference in net contents between the two products, not the actual nutritional value.

(Response 12) We recognize that certain differences will appear on product labels between the amounts of nutrients per serving listed on products that contain close to, but less than, 200 percent of the RACC, and products that contain 200 percent of the RACC or more. Allowing products that contain less than 200 percent of the RACC to voluntarily display an additional column with nutrition information per common household measure that most closely approximates the reference amount will allow consumers to easily compare the nutrition information of products containing more than 150 percent but less than 200 percent of the RACC with products that contain 200 percent of the RACC or more. Therefore, we are amending § 101.9(b)(6) to add a provision that allows manufacturers of products that contain more than 150 percent and less than 200 percent of the applicable reference amount to voluntarily add a second column of nutrition information to the left of the column that provides nutrition information per container (i.e., per serving) that will provide nutrition information per common household measure that most closely approximates the reference amount. This provision will allow consumers to compare more easily the nutrition information amongst similar products that are packaged in containers that are near 200 percent of the RACC by allowing manufacturers to use a similar dual-column label format. This voluntary labeling provision is not limited to large-RACC products, but is permitted for all products that are packaged and sold individually in containers that are more than 150 percent and less than 200 percent of the RACC.

With regard to the concern that products of nearly identical size could appear to have significantly different amounts of nutrients per serving due to the fact that some products could be required to be labeled as a single serving while similar products could be labeled as having

two servings, we note that the dual-column labeling requirements (see section III.C.) will help ensure that consumers have the opportunity to compare the nutritional information for the package as a whole for products containing at least 200 percent and up to and including 300 percent of the RACC with the serving size for those products containing just under 200 percent of the RACC.

To address the comment that stated that a lower net content in some product manufacturing would cause consumers to think that a certain product has a better nutritional profile than another, we note that the nutrition information that is provided on these products would still be accurate. If the net content is lower, the amount of product a person is likely to consume is also lower, which is reflected in the nutrition information on the label.

(Comment 13) We received numerous comments that supported the removal of the exemption for large-RACC products from the definition of a single-serving container. These comments stated that products containing less than 200 percent of the RACC are likely to be consumed in a single eating occasion and should be labeled as a single serving.

Several comments opposed the removal of language from § 101.9(b)(6), which gives manufacturers the flexibility to label large-RACC products that contain more than 150 percent but less than 200 percent of the RACC as 1 or 2 servings, or to label packages that contain 200 percent or more of the applicable RACC as a single serving if the contents of the entire package can reasonably be consumed at a single eating occasion. The comments stated that eliminating this option takes away a manufacturer's flexibility and asserted that manufacturers are in the best position to determine if a product should be labeled as one or two servings. Other comments stated that labeling products with less than 200 percent of the RACC as one serving may not be appropriate for all foods. For example, several comments stated that some side dishes, such as

frozen potato products, frozen vegetables, and macaroni and cheese kits, are consumed in smaller quantities than entrée items, and a consumer could not reasonably consume an amount close to 200 percent of the RACC.

A few comments objected to requiring products that were previously labeled as two servings to be labeled as one serving and asserted there was no change in consumption data. Other comments did not like the “one size fits all” approach and suggested that we look at actual usage of each product category before requiring that a product be labeled as a single serving. One comment noted that labeling products that are regulated by FDA and the USDA, such as chili, soup, stews, and several mixed dishes that often come in 15 oz cans (425 g), as a single serving would be a shift from the industry standard of labeling cans of this size as containing “about 2 servings.”

(Response 13) We disagree with the comments opposing the removal of the option of large-RACC products (i.e., those products with an RACC of 100 g or 100 mL or larger) that contain more than 150 percent but less than 200 percent of the RACC to be labeled as one or two servings. We also disagree with the assertion that there has been no change in consumption data since 1993. We stated in the 1993 serving size final rule that we agreed with the comments that the 200 percent cutoff level may be too high for some products with large RACCs. Further, we stated that the reference amounts of these products are very large compared to many other products, and examination of food consumption data showed that the average variability (defined as the standard deviation as a percent of the mean) in the amount customarily consumed for foods having a reference amount of 100 g (or mL) or larger is about two-thirds of the variability for foods having a reference amount less than 100 g (58 FR 2229 at 2233). In other words, in 1993, we concluded that it was much less likely that a person would consume approximately

twice the reference amount of a food with a reference amount of 100 g (or mL) or more, than it was that he or she would consume approximately twice the reference amount of a food with a smaller reference amount. Therefore, in the 1993 serving size final rule, we concluded that, for those products that have large RACCs, 150 percent may be a reasonable cutoff for a single-serving container (58 FR 2229 at 2233).

However, as discussed previously in this document, in developing the proposed rule, we examined the correlation between the consumption variation and the RACCs for all products containing less than 200 percent of the applicable RACC, including the products with large RACCs and products that have RACCs that are less than 100 g (or mL), using combined consumption data from the NHANES 2003-2008 surveys (Ref. 9). The result shows that the correlation coefficient is 0.13, which means that there is a low correlation between the RACCs (whether the reference amount is more than or less than 100 g or mL) and the consumption variation for all products containing less than 200 percent of the RACC, regardless of whether the RACC is “large.” In other words, it is not less likely that a person would consume approximately twice the reference amount of a food with a large RACC than it is that he or she would consume approximately twice the reference amount of a food with a smaller reference amount. Therefore, we determined that the exemption from the requirement to label a product with a large RACC that contains more than 150 percent but less than 200 percent of the applicable RACC as a single-serving container is no longer warranted. We are also working with USDA to harmonize our regulations.

In response to the comments that stated that we are reducing the flexibility of our regulations, although we work to increase the flexibility of our regulations when appropriate, the purpose of this option was not to allow manufacturers the ability to make a choice, but to allow

for foods to be labeled in a way that reflects how much a person is consuming a certain product. Our decision to remove this option is based on the data indicating that consumers are consuming the same amount of large-RACC products in proportion to the RACC as they are of smaller-RACC products in proportion to the RACC.

To address the comments that stated that not all foods that are less than 200 percent of the RACC should be considered a single serving, we reiterate that research demonstrates that package and portion sizes tend to have a considerable impact on the amount of food consumed (Refs. 10 and 11). We also note that we did not propose to change the upper limit for the definition of a single serving container in the serving size proposed rule. Additionally, as explained in comment 12, we are amending § 101.9(b)(6) to allow manufacturers of products that contain more than 150 percent and less than 200 percent of the applicable reference amount to voluntarily add a second column of nutrition information to the left of the column that provides nutrition information per container, which will provide nutrition information per common household measure that most closely approximates the reference amount.

(Comment 14) Some comments stated that requiring products that were previously labeled as two servings to be labeled as one serving would encourage consumers to eat more. One comment asserted that the information on the label of a single-serving container could discourage consumption of a particular food product due to the quantity of a specific nutrient in the container or other information about the product, while on the whole that product could provide valuable nutrients in the diet. The comment gave an example of a frozen entrée that may be high in saturated fat, yet be a good source of protein, dietary fiber, and potassium. The comment stated that, if consumers were to focus only on the saturated fat content of the product,

they may choose not to eat the frozen entrée, even though it is a good source of other essential nutrients.

(Response 14) As noted previously, research demonstrates that package and portion sizes tend to have a considerable impact on the amount of food consumed (Refs. 10 and 11). We acknowledge that certain consumers may pay attention to specific, individual nutrients, but one of the main goals of nutrition labeling is to provide consumers with accurate nutrition information to assist them in maintaining healthy dietary practices. If a product is high or low in a specific nutrient for which an individual consumer is looking to either increase or decrease intake, this information is useful to consumers who are interested in the specific nutrient. Consumer education on understanding the Nutrition Facts label and the diet can be used to help explain the benefits and risks associated with the intake of nutrients. Additionally, for products that satisfy the requirements to make a nutrient content claim such as a “good source” claim (see 21 CFR 101.54), the product may include such a claim to draw attention to the positive attributes of the product.

C. Dual-Column Labeling

Preexisting § 101.9 provides various provisions for types of voluntary dual-column labeling (e.g., paragraphs (b)(10), (e), and (h)(4)) and one provision for mandatory dual-column labeling under certain circumstances (paragraph (b)(11)). In comment 10 we discuss a revision in this final rule to the voluntary dual-column labeling provision in § 101.9(b)(10)(ii), which broadens the scope of the provision to allow dual-column labeling per unit for single-serving products. Also, in comment 12 we discuss a new voluntary provision for dual-column labeling for products that are packaged in containers that include more than 150 percent but less than 200 percent of the RACC, in § 101.9(b)(6).

In the preamble of the proposed rule (79 FR 11989 at 11998 to 11999), we cited research that shows that dual-column labeling with the nutrition information given per serving and per package may help certain consumers recognize nutrient amounts per package in certain types of packaged foods (Refs. 14 and 15). In the preamble of the proposed rule (79 FR 11989 at 11999), we also discussed consumer research that we conducted to help increase our understanding of whether modifications to the label format may help consumers use the label. Our study compared participants' ability to perform various tasks, such as evaluating product healthfulness and calculating the number of calories and other nutrients per serving and per container, when using the current label versus modified versions of the current label. The main findings from this study are that the availability of single-serving-per-container labels and dual-column labels resulted in more participants correctly identifying the number of calories per container and the amount of other nutrients per container and per serving compared to single-column labels that listed two servings per container.

The proposed rule would require, under certain circumstances, the use of dual-column labeling to provide nutrition information per serving and per container (proposed § 101.9(b)(12)(i)), or per serving and per unit of food (proposed § 101.9(b)(2)(i)(D)). As noted in the preamble of the proposed rule, such dual-column labeling will provide nutrition information for those who consume the entire container in one eating occasion as well as those who consume the container over multiple eating occasions or share the container with others (79 FR 11989 at 12003).

In the preamble of the proposed rule we stated that to determine an upper limit for the range of package sizes for which dual-column labeling would be required, we looked at food consumption data from NHANES 2003-2008 surveys (Ref. 16) (79 FR 11989 at 12003). The

intake distribution per eating occasion for each product showed that for almost all products, regardless of the amount of the RACC, the ratio of the intake at the 90th percentile level to the RACC was 400 percent or less. Therefore, we determined that dual-column labeling for packages containing at least 200 percent of and up to and including 400 percent of the RACC would capture the most frequent consumption habits for almost all product categories.

Conversely, the data show that products that contain more than 400 percent of the current RACC are less likely to be consumed in one eating occasion compared to products that contain 400 percent or less of the current RACC. Therefore, we proposed dual-column labeling to be required for all packages that contain at least 200 percent of and up to and including 400 percent of the applicable RACC (proposed § 101.9(b)(12)(i)).

In the preamble of the proposed rule (79 FR 11989 at 12004) we requested comment on exemptions from dual-column labeling for products that require further preparation, such as macaroni and cheese kits, pancake mixes, pasta products, and for products that are commonly consumed in combination with other foods (e.g., cereal and milk), and that contain at least 200 percent and up to and including 400 percent of the applicable RACC. Under our regulations, nutrition information for these types of products may be presented for two or more forms of the same food (e.g., both as “purchased” and “prepared”) (§ 101.9(e)). Some of these products voluntarily contain two columns of nutrition information on the “as purchased” and “as prepared” forms of the food. Therefore, we tentatively concluded in the proposed rule that these types of products that require further preparation and voluntarily include two columns of nutrition information on the “as purchased” and “as prepared” forms of the food, and for products that are commonly consumed in combination with other foods (e.g., cereal and skim milk) (§ 101.9(h)(4)) should be exempt from the dual-column labeling requirements.

In § 101.9(b)(12)(ii) we proposed to require that if a health or nutrient content claim is made on the label of a product that uses dual-column labeling, as would be required under proposed § 101.9(b)(12)(i) and (b)(2)(i)(D), the claim would be required to be followed by a statement that sets forth the basis on which the claim is made if the product qualifies for the claim based on the amount of the nutrient per RACC and not the amount in the entire container or unit of food (e.g., for nutrient content claims, “good source of calcium” “a serving of __ oz. of this product contains 150 mg of calcium” or, for health claims, “A serving of __ ounces of this product conforms to such a diet”).

As noted previously in the introduction to section III.B., we also proposed to remove the text in preexisting § 101.9(b)(2)(i)(D), which states that if a unit weighs 200 percent or more of the RACC, the manufacturer may declare one unit as the serving size if the entire unit can reasonably be consumed in one eating occasion. Proposed § 101.9(b)(2)(i)(D) states that if a unit weighs at least 200 percent and up to and including 400 percent of the applicable reference amount, the manufacturer must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent DVs for the individual unit, as well as the preexisting columns listing the quantitative amounts and percent DVs for a serving that is less than the unit (i.e., the serving size derived from the RACC).

1. General Comments on Dual-Column Labeling

(Comment 15) We received several comments in support of the dual-column labeling requirements as proposed. The comments stated that because consumers may eat a full package of food regardless of its serving size, those consumers must be able to easily understand the nutrition content of the full package of food as consumed. A few comments stated that consumers who might otherwise simply assume that the Nutrition Facts label applies to the entire

package would see, at a glance, that the nutrition information for the entire package is considerably greater than the serving size. These comments stated that seeing two sets of nutrition information per serving and per container could prompt people to think about the portion size they are consuming.

Some comments mentioned specific food product categories that they thought would be ideal for dual-column labeling because they are sometimes consumed by a single person in one eating occasion and sometimes eaten over multiple meals or by multiple people. The products mentioned in the comments included pints of ice cream, frozen pizzas, main entrées, side dishes, frozen vegetables, bags of chips, large candy bars, snack foods, cookies, and 20 oz sodas.

(Response 15) We agree that dual-column labeling will help consumers more easily understand the contents of a particular package both on a per-serving and per-container basis. As discussed in the introduction to section III.C., research suggests that dual-column labeling helps consumers understand the amount of nutrients in an entire container of food. The foods that were listed in the comments as being appropriate for dual-column labeling are similar to the foods that were mentioned in the April 4, 2005, Advance Notice of Proposed Rulemaking (ANPRM) entitled “Food Labeling: Serving Sizes of Products that Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes” as foods that consumers thought were single servings, but were really multiple servings (70 FR 17010 at 17013). To the extent these comments suggest that the requirements relating to dual-column labeling should apply only to certain types of products, we disagree. This issue is addressed in our response to comment 19.

(Comment 16) We received several comments that opposed the additional wording that we proposed to require in § 101.9(b)(12)(ii) if a health or nutrient content claim is made on a

product containing a dual-column label. The comments asserted that the proposed statements are too lengthy and unnecessary, would clutter the label and take focus away from information in the claim, and would create inconsistency across package sizes. The comments asserted that there is no consumer research to establish that nutrient content claims on dual-column labels present the potential for consumer confusion (i.e., without the “basis” language), that consumers would believe that the claims are based on an entire container in the event dual-column labeling were used, or that the proposed language would assist consumers in understanding the basis for the claim. The comments further questioned whether we had an adequate legal basis for requiring the proposed explanatory statement and noted that there is a current regulation that allows for indicating the basis of a claim if the claim is not based on the RACC. A few comments indicated that if some type of statement becomes necessary, then it should be very simple and short, such as the addition of “per serving” or “per X oz. serving.” We received one comment in support of the statement as proposed. We received one comment that requested we limit the qualifying statement to nutrient content claims about the absence of a nutrient (e.g., low fat), as when these type of claims are made on products that include a dual-column label, the product would only meet the criteria for the claim on the basis of the RACC and per labeled serving, but not the entire container.

(Response 16) We do not agree that a statement explaining the basis of a nutrient content claim or health claim, as described in proposed § 101.9(b)(12)(ii), is always unnecessary. Because the use of dual-column labeling per serving and per container will become more prevalent on food labels, consumers will more often encounter nutrition claims on foods with dual-column labeling. When consumers encounter a nutrient content claim or health claim (e.g., low fat) and are also presented with two sets of nutrition information (i.e., per serving

information and per container information), and the criteria for the claim would only be met based on the set of nutrition information that does not apply to the entire container or unit, as applicable, explanation is needed to avoid consumer deception and clarify which set of nutrition information the claim applies to. When the claim relates to the nutritional information presented in one column, but not the other, the possibility for consumer deception is self-evident. Due to the expected use of nutrient content claims and health claims on products using dual-column labeling, we want to ensure that consumers understand the basis on which the claim is made. We are authorized to prohibit claims that are false or misleading under sections 403(a) and 201(n) of the FD&C Act. See also Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 593 (1980) (explaining that “false and misleading commercial speech is not entitled to any First Amendment protection”). Current provisions for claims require a manufacturer to communicate if a product meets the criteria for a nutrient content claim or health claim only on the basis of the reference amount (e.g., a product with a serving size of 2 cookies weighing 35g, but that only meets the criteria for a nutrient content claim based on the 30 g RACC for cookies) (§ 101.12(g)), but there are currently no provisions which require a claim to explain which set of nutrition information it is based on in the context of dual-column labeling. When a nutrient content claim or health claim is made on a package that does not use dual-column nutrition labeling, consumers are provided with only one set of nutrition information (based on the serving size) in the Nutrition Facts label to associate with the claim. In the case of dual-column labeling, however, consumers are presented with two sets of nutrition information and would not be able to determine which set of data to associate with the claim. Therefore, in order to help consumers understand the context of the claim, there is a need for a provision requiring a statement that sets

forth the basis on which the claim is made under certain circumstances when dual-column labeling is presented on the product label.

We agree, however, that the proposed statements could be lengthy. The comments provided examples of concise language that could accompany nutrient content claims and still meet the objective of indicating the basis of the claim. We agree that, when possible, shorter clarifying statements on the food label are preferable and that more concise language than that in proposed § 101.9(b)(12)(ii) is available for nutrient content claims. Therefore, for nutrient content claims, § 101.9(b)(12)(ii) requires manufacturers to state that the claim refers to the amount of a nutrient per serving or per reference amount but allows the use of simpler language to explain the basis on which nutrient content claims are made per serving (e.g., “good source of calcium per serving” or “per X [insert unit]__serving”) or per reference amount (e.g., “good source of calcium per [insert reference amount (e.g., per 8 ounces)]”), as required based on § 101.12(g). For health claims, no examples of more concise language were provided in comments to the proposed rule, and upon further evaluation of the explanatory statement provided in the proposed rule (i.e., “A serving of __ ounces of this product conforms to such a diet”), we believe that the statement is as concise as possible to convey the intended message. Health claims, as opposed to nutrient content claims, already frequently require informational statements related to the substance of the claim, the disease condition, and/or the target populations. Therefore, we conclude that the statement related to the basis of the claim, as proposed, is an appropriate statement to include with health claims, is consistent with other types of accompanying statements to health claims, and is as concise as needed for the intended message.

With regard to the assertion that the additional wording that we proposed to require in § 101.9(b)(12)(ii) if a health or nutrient content claim is made on a dual-column label would create inconsistency across package sizes, we note that distinctions already may arise among products of different sizes with regard to which package sizes are eligible to bear a nutrient content or health claim. Claims are typically based on the RACC, but in some cases they are based on both an RACC and a per label serving size. Existing requirements may already result in differences in the eligibility of a food packaged in different forms (e.g., bulk package versus individual serving packages) to bear a specific claim. Likewise, differences exist with regard to the ability of products to make nutrient content or health claims because of the variety of possible size options (e.g., one very large cookie versus an individual serving container of small cookies).

With regard to the comment that suggested the requirement to include the qualifying statement should be limited to nutrient content claims about the absence of a nutrient, we disagree with establishing a limitation based on the specific claim at issue (e.g., low fat) but agree with the comment to the extent that it suggests that the qualifying statement should not be required on product labels when the product would meet the criteria to make the claim at issue based on both columns of nutritional information. We agree, for example, that if a product for which dual-column labeling would be required under § 101.9(b)(12)(i) were to contain sufficient vitamin C per serving to make a “high” claim regarding vitamin C content, and the container as a whole were to meet the criteria for a “high” in vitamin C claim, consumers are not likely to be misled by the presence of such a claim in the absence of a qualifying statement. The language in proposed § 101.9(b)(12)(ii) already provides an exception from the requirement for products when the nutrient that is the subject of the claim meets the criteria based on the entire container

or unit amount. We have modified that language in the final rule to explain that a clarifying statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on the reference amount for the product and the entire container or the unit amount.

(Comment 17) One comment questioned our legal authority to require dual-column labeling. The comment stated that section 403(q)(1)(A)(i) of the FD&C Act requires nutrition information to be provided on the basis of an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food. The comment stated that the quantity of nutrients in a package or unit that contains at least 200 percent and up to and including 400 percent of the RACC is not an amount customarily consumed and that none of the exemptions stated in the NLEA give us the authority to require nutrition information to be declared on the basis of an amount other than the serving size.

(Response 17) We disagree with the suggestion that we lack the legal authority to require dual-column labeling. The mandatory dual-column label will continue to provide nutrition information based on the labeled serving size, which is the amount that is customarily consumed. As explained previously in section II.B., the primary legal authority for requirements pertaining to the labeled serving size is derived from section 403(q)(1)(A) of the FD&C Act, with additional authority coming from section 2(b)(1)(B) of the NLEA. Additionally, the legal authority for the second column in a dual-column label is derived from section 2(b)(1)(A) of NLEA, which states that requirements in regulations issued under the authority of the NLEA shall “be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet” (79 FR 11989 at 11991). As explained previously in section III.C. and in the

preamble to the proposed rule (79 FR 11989 at 11999), consumer research shows that the availability of dual-column labels results in more participants correctly identifying the number of calories per container and the amount of other nutrients per container compared to single-column labels that listed two servings per container. Additional authority for the dual-column labeling requirements includes section 701(a) of the FD&C Act, which provides us with authority to issue regulations for the efficient enforcement of the FD&C Act.

(Comment 18) One comment asserted that we failed to consider certain First Amendment concerns associated with the proposed dual-column labeling requirements. The comment asserted that the purpose of dual-column labeling is to shape consumer behavior rather than to provide purely factual information, and that we justified our proposal to require dual-column labeling based on a study that concluded that dual-column labeling reduces snack food consumption when compared to single-column labeling for people who are not currently dieting. The comment stated that by explaining that we would continue to conduct consumer research throughout the rulemaking process to help enhance our understanding of whether and how much any modifications to the label format may help consumers use the label, we impliedly conceded the insufficiency of our reliance on this study in the proposed rule.

The comment further questioned our asserted reliance on statutory authority granted in section 2(b)(1)(A) of the NLEA in light of our mandate to implement regulations in accordance with the First Amendment. The comment asserted that because dual-column labeling “is unnecessarily duplicative,” the dual-column labeling requirement would be subject to analysis under the standard set forth in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n, 447 U.S. 557 (1980), rather than Zauderer v. Office of Disciplinary Counsel of Supreme Court, 471 U.S. 626 (1985). The comment asserted that the Supreme Court’s decision in Zauderer and its

progeny supports the proposition that the government may require a clarifying disclosure “to dissipate the possibility of consumer confusion or deception” after finding that the possibility of deception is “self-evident,” *id.* at 652, and that mandatory disclosures are not permitted unless the state demonstrates an actual likelihood that consumers will be misled absent the disclosure.

The comment asserted that we admitted that the dual-column labeling requirement attempts to influence consumer behavior by discouraging consumers from consuming food that is packaged between 200 percent and 400 percent of the RACC. The comment stated that we failed to establish that dual-column labeling would serve a substantial government interest in discouraging consumption of food that is packaged between 200 percent and 400 percent of the RACC. The comment further asserted that we failed to establish in the proposed rule that dual-column labeling would have a discernable effect on consumer behavior and, therefore, that the proposed rule cannot satisfy the third prong of Central Hudson in that it did not present evidence that dual-column labeling would directly advance the interest in promoting consumer health and preventing overconsumption of certain foods. The comment stated that we rely in part on study results suggesting that dual-column labeling reduces snack food consumption but asserted that we failed to consider the effect of dual-column labeling on consumption of other categories of food besides snacks. According to the comment, we inexplicably concluded, based on studies of “junk foods”, that consumption of all foods packaged as RACCs between 200 percent and 400 percent should be discouraged.

The comment asserted that the dual-column labeling requirement as proposed is “vastly overbroad” and fails to satisfy Central Hudson’s reasonable fit test, in part because we acknowledged in the proposed rule that modifying the Nutrition Facts label would require some reeducation on how to read the Nutrition Facts label. The comment asserted that we failed to

adequately consider comments that suggested that the dual-column format may be confusing and that we erroneously suggested that the burden is on opponents of the regulation to provide evidence that dual-column labeling may be confusing.

(Response 18) We recognize the importance of the First Amendment protections raised in this comment, and we disagree with the assertion that we neglected to consider such protections in proposing the dual-column labeling requirements. In Zauderer, the Supreme Court explained that “[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a speaker’s] constitutionally protected interest in not providing any particular factual information in his advertising is minimal.” 471 U.S. at 651 (emphasis in original) (internal citations omitted). Requirements “to make purely factual disclosures related to...business affairs, whether to prevent deception or simply to promote informational transparency, have a ‘purpose...consistent with the reasons for according constitutional protection to commercial speech’...[and] facilitate rather than impede the ‘free flow of commercial information.’ ” Beeman v. Anthem Prescription Mgmt., 58 Cal. 4th 329, 356 (Cal. 2013) (quoting 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 501 (1996) and Va. Pharmacy Bd. v. Va. Consumer Council, 425 U.S. 748, 765 (1976), respectively). As a result, government requirements to disclose factual commercial information are subject to a more lenient constitutional standard than that set forth under the Central Hudson framework. Zauderer, 471 U.S. at 651. Under Zauderer, the government can require disclosure of factual information in the realm of commercial speech as long as the disclosure provides accurate, factual information; is not unjustified or unduly burdensome; and is "reasonably relate[d]" to an adequate interest. Id.

Contrary to the comment's assertion, the validity of the dual-column labeling requirements under the First Amendment is properly evaluated under Zauderer, 471 U.S. 626, rather than Central Hudson, 447 U.S. 557. Courts generally apply Zauderer's rational relationship test, as opposed to intermediate scrutiny under Central Hudson, "in compelled commercial disclosure cases" because "mandated disclosure of accurate, factual, commercial information does not offend the core First Amendment values of promoting efficient exchange of information or protecting individual liberty interests." Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 114-15 (2d Cir. 2001) (explaining that the disclosure of accurate, factual commercial information "furthers, rather than hinders, the First Amendment goal of the discovery of truth"). Case law interpreting Zauderer clarifies that the government need not establish that compelled disclosure will prevent consumer deception for the Zauderer standard to apply. In American Meat Institute v. USDA, the court held that "[t]he language with which Zauderer justified its approach...sweeps far more broadly than the interest in remedying deception." 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc). In reaching the conclusion that the applicability of Zauderer extends beyond regulations in which the government is attempting to mandate a disclosure to remedy deception, the court focused on the "material differences between disclosure requirements and outright prohibitions on speech," id. (quoting Zauderer, 471 U.S. at 650), the fact that "the First Amendment interests implicated by disclosure requirements are substantially weaker than those at stake when speech is actually suppressed," id. (quoting Zauderer, 471 U.S. at 652 n.14), and the fact that "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, [a] constitutionally protected interest in not providing any particular factual information in his advertising is minimal," id. (citing Zauderer, 471 U.S. at 651). The court found that, "[a]ll told,

Zauderer's characterization of the speaker's interest in opposing forced disclosure of such information as 'minimal' seems inherently applicable beyond the problem of deception." Id. Several other circuits concur. See Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 297-98, 310, 316 (1st Cir. 2005); N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (affirming use of the "reasonable-relationship" Zauderer standard when "the compelled disclosure at issue... was not intended to prevent 'consumer confusion or deception'"); Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 556 (6th Cir. 2012) (holding that "Zauderer's framework can apply even if the required disclosure's purpose is something other than or in addition to preventing consumer deception"); CTIA--The Wireless Ass'n® v. City of Berkeley, No. C-15-2529, 2015 U.S. Dist. LEXIS 126071, at *46 (N.D. Cal. 2015) (holding that Zauderer is not "limited to preventing consumer deception" and explaining that "it would make little sense to conclude that the government has greater power to regulate commercial speech in order to prevent deception than to protect public health and safety").

The dual-column labeling requirements readily satisfy the Zauderer test. First, the proposed dual-column labeling provisions, which are being finalized in this rule, require accurate disclosures of factual commercial information. The required disclosure will help facilitate the free flow of commercial information and does not "prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion." Zauderer, 471 U.S. at 651 (quoting W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943)). The comment did not dispute the accuracy of the information at issue.

Second, the dual-column labeling requirements would not be unduly burdensome. Factual nutrition information is currently required to be provided on packaged foods. While

dual-column labeling will require more space on certain packages for factual nutrition information, the majority of the label space on products subject to the dual-column labeling requirements will still be available for product messaging by the manufacturer. We also note that, as discussed in our economic analysis (Ref. 17), the cost to manufacturers is relatively low under the compliance timelines in the final rule which will allow most manufacturers to add dual-column labeling during regularly scheduled label changes for their products. Additionally, this final rule reduces from the proposed rule the amount of products for which dual-column labeling will be required, as we are lowering the upper limit for which dual-column labeling is required from those containers weighing up to 400 percent of the RACC to those containers weighing up to 300 percent of the RACC. Furthermore, certain packages for which dual-column labeling would require a greater proportion of the label space are exempt from these requirements. For example, under § 101.9(b)(12)(i)(A), the dual-column labeling requirements in § 101.9(b)(12) do not apply to products that meet the requirements to present the Nutrition Facts label using the tabular format under current § 101.9(j)(13)(ii)(A)(1) or the linear format under current § 101.9(j)(13)(ii)(A)(2).

Third, the requirement to provide dual-column labeling is reasonably related to the Government's interests in promoting the public health and providing consumers access to factual information that will help them understand the nutrient content on certain packages that contain more than one serving of food. The factual information could be used to assist consumers in maintaining healthy dietary practices. Recent NHANES data shows that products containing up to and including 300 percent of the RACC could reasonably be consumed in a single eating occasion. Additionally, our research demonstrates that some consumers may have difficulties determining nutrition information per container when a label declares that the package contains

more than one serving and is reasonably consumed in a single eating occasion. Our recent format experimental study, however, showed that, in the case of a proposed label with percent DVs listed on the left of the label, dual-column labeling improved the percentage of participants that were able to identify correctly the amount of nutrients in the entire container. In addition, our recent eye-tracking study showed participants both the current and proposed format of the Nutrition Facts labels, with one label showing one serving and the other two servings. Only about half of the participants noticed the number of servings on the label, and less than one third of the participants were able to identify which product contained fewer calories per container (Refs. 18 and 19). These results suggest that some consumers may not correctly recognize the accurate nutrient contents of packages containing more than one serving, including packages that may be consumed in a single eating occasion, and therefore may not be able to use the label information to assist them in maintaining healthy dietary practices.

The dual-column labeling requirement is reasonably related to the Government's interest in enhancing consumer understanding of nutrient packaging and promoting the public health because it presents nutrition information in a manner that is easy to understand, giving consumers helpful tools to assist them in maintaining healthy dietary practices. As noted previously, our research shows that some consumers have difficulty determining the nutrient amounts in packages that contain more than one serving of food and that do not display the nutrient content of the entire package on the product label. Dual-column labeling helps to ensure that consumers have access to nutrient information for containers of certain sizes that could reasonably be consumed in a single eating occasion and therefore could assist consumers in maintaining healthy dietary practices.

The comment incorrectly asserts that the purpose of the proposed dual-column labeling requirements is to shape consumer behavior by discouraging consumption of food in containers that weigh between 200 percent and 400 percent of the reference amount. As explained in the proposed rule (see 79 FR 11989 at 12003), and as reiterated in this final rule, the purpose of dual-column labeling is not to discourage the consumption of certain foods but rather to increase consumer understanding of the quantity of nutrients in packages and containers of certain sizes that may be reasonably consumed in a single eating occasion. The reference provided in the proposed rule to a study that showed a reduction in snack food consumption amounts was included for the purpose of demonstrating that dual-column labeling could raise contextual awareness of the quantity of nutrients in a given container. While the reduction in the consumption amounts for certain products could potentially be associated with dual-column labeling, such changes in consumption are not the purpose of the requirement. Our findings, both as reported in the proposed rule and as explained previously in this final rule, demonstrate that the presence of dual-column labeling could help consumers understand the quantity of nutrients they are actually consuming if they consume the entire package in one eating occasion. Consumption data further shows that it is reasonably likely that some consumers will consume, in a single eating occasion, the entire container of products containing at least 200 percent and up to and including 300 percent of the RACC. We therefore disagree with the assertion that the dual-column labeling requirement “is unnecessarily duplicative” or that our reliance on the statutory authority granted in section 2(b)(1)(A) of NLEA conflicts with our obligation to promulgate regulations consistent with the protections granted by the First Amendment. Additionally, as discussed in the preamble to the proposed rule (79 FR 11989 at 11998), there is evidence that consumers do not correctly calculate nutrient amounts in food products by

multiplying the nutrient amount by the number of servings per container, and research shows that dual-column labeling can help consumers more accurately determine the number of calories and nutrients in a food product compared to single-column labeling (Ref. 15). In short, dual-column labeling provides consumers with information that can assist them in maintaining healthy dietary practices.

While we disagree that the Central Hudson standard would be applicable to the requirement to provide a second column of nutrition information, the requirement to provide dual-column labeling would nonetheless be Constitutional under the standard set forth in Central Hudson, 447 U.S. 557. If the Central Hudson standard were applicable to the evaluation of the dual-column labeling requirement, we would be required to identify a “government interest [that] is substantial,” establish that “the regulation directly advances the government interest asserted,” and show that the regulation “is not more extensive than is necessary to serve that interest.” Id. at 566. Under the Central Hudson test, we have the discretion to “judge what manner of regulation may best be employed” to serve the substantial government interest. See City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 416 n.12 (1993) (citing Bd. of Trs. v. Fox, 492 U.S. 469, 480 (1989)).

There can be no question that the government has a substantial interest in promoting the health of its citizens. E.g., Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995). Our asserted interests are in promoting the public health and ensuring consumer access to information that could assist in maintaining healthy dietary practices. These interests are substantial because the consumption of excess and limited amounts of certain nutrients is linked to risk of chronic disease.

Dual-column labeling directly advances our asserted interests in promoting the public health and ensuring that consumers have access to information that could assist in maintaining healthy dietary practices. Our research shows that providing a second column of nutrition information on containers of certain sizes provides consumers information that allows them to understand the nutrient content of packaged foods. We disagree that our decision is based on “mere speculation or conjecture.” See Rubin, 514 U.S. at 487. Our conclusion that dual-column labeling helps consumers understand the nutrient content of packaged foods when a label declares the package contains more than one serving and is reasonably consumed in a single eating occasion is supported by the consumer research cited throughout this document (Refs. 13 and 17).

Finally, the requirement to provide a second column of nutrition information is no more extensive than necessary to serve its purpose. See Central Hudson, 447 U.S. at 566. The standard is not a “least restrictive means” test, and instead requires a reasonable fit between the ends and the narrowly tailored means chosen to accomplish those ends. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 556 (2001). The dual-column labeling requirement requires only factual disclosures of information about the nutrient content of products, and the required disclosure is limited to the information that we have determined is necessary to assist consumers in maintaining healthy dietary practices. The required disclosure is confined to one area of the food label and will enable consumers to understand the information in the Nutrition Facts label. Overall, this additional factual disclosure is limited in scope, and there are not “numerous and obvious less-burdensome alternatives” to this requirement. See Discovery Network, 507 U.S. at 418 n. 13. In our research we looked at labels that provided a second column only for calories. Our research showed that this type of label was not as effective as providing a full second

column of information about all nutrients listed on the Nutrition Facts label because different consumers are mindful of distinct nutrients and because the nutritional benefits of a product does not depend on a limited number of nutrients only. For example, some consumers need to ensure adequate consumption of specific vitamins or minerals, while others are concerned about protein intake. Full, dual-column nutritional information is more helpful to consumers and does not suggest that consumers should place greater emphasis only on selected nutrients. We therefore disagree with the implication that this requirement is more burdensome than necessary because it requires the full set of nutritional information in the second column. Requiring that a second column of nutrition information appear on the label is a limited requirement that would serve the purpose of ensuring that consumers have access to information about the nutrient contents of packages and containers of certain sizes that could assist consumers in maintaining healthy dietary practices.

We disagree with the comment's assertion that the dual-column labeling requirement is "vastly overbroad," which the comment asserts is demonstrated by our intent to conduct consumer education once the rule is finalized. Such education efforts are beneficial any time such a significant change in our regulations is made, and the addition of a second column of nutrition information is not the sole basis for our plan to continue to educate consumers. Additionally, as noted previously, certain packages for which dual-column labeling would require a greater proportion of the label space are exempt from these requirements (see § 101.9(b)(12)(i)(A)).

Because the dual-column labeling requirement supports a government interest that is substantial, directly advances that government interest, and is no more extensive than is necessary to serve that interest, the requirement would pass Constitutional scrutiny under Central

Hudson. However, as noted previously in this section, case law makes clear that Zauderer applies to cases in which the government mandates the disclosure of factual and accurate disclosures of commercial information, Zauderer, 471 U.S. at 651, as is the case here.

With regard to other specific issues raised in this comment, we disagree with the assertion that by explaining that we would continue to conduct consumer research throughout the rulemaking process we impliedly conceded the insufficiency of our consumer research cited in the proposed rule. The consumption data and research cited in the proposed rule provides sound justification for dual-column labeling. Additionally, since the publication of the proposed rule, we have conducted an additional study that corroborates the results discussed in the proposed rule, i.e., that consumers were more likely to accurately determine the amount of nutrients shown on a label when dual-column labeling was used (Ref. 19). We continued to conduct research throughout the rulemaking process because the Lando and Lo study used the current format and we wanted to explore whether findings derived from that study would replicate on a different label format as outlined in our proposed rule. The subsequent study did, in fact, replicate the original finding that more consumers were able to accurately identify the amount of total nutrients shown on a product label when using the dual-column label, as compared to a single-column label with multiple servings per container (Ref. 15).

We further disagree with the assertions that we justified our proposal for dual-column labeling based on one study or that our conclusions for dual-column labeling are based solely on a study of snack foods. In addition to the studies discussed in the previous paragraph, we received a citizen petition and many comments to the ANPRM from consumers that said that labeling products that were considered to be single servings as having two or more servings is “confusing” and “misleading.” We also note that the labels tested in the Lando and Lo study

(Ref. 15), which were also cited in the proposed rule, included sample Nutrition Facts labels for frozen meals, which are not considered “snack foods.” Dual-column labeling would require certain containers to display easy-to-understand nutrition information for the primary ways in which people consume these products. The studies that were cited in the proposed rule were used as part of the support for the need for dual-column labeling, not as our sole justification for dual-column labeling.

Finally, we disagree that dual-column labeling may be confusing to consumers, that we failed to consider comments that suggested dual-column labeling may be confusing, and that we have suggested that those who are looking to challenge the dual-column labeling requirements have the burden to provide evidence that dual-column labeling may be confusing. As discussed previously in this document, our research has shown that single-serving-per-container labels and dual-column labels resulted in more participants correctly identifying the number of calories per container and the quantity of other nutrients per container and per serving compared to two-serving, single-column labels (such as the current label) (Ref. 19).

2. Dual-Column Labeling Requirements

(Comment 19) We received several comments from manufacturers objecting to 400 percent of the RACC as the upper limit for mandatory dual-column labeling.

Several comments suggested that we consider the type of product at issue in establishing an upper limit. Some of the comments stated that an upper limit of 400 percent of the RACC was not appropriate for all product categories. Other comments stated that dual-column labeling should only be required for certain types of products. A few comments objected to what they called a one-size-fits-all approach to applying the dual-column labeling requirements. One comment stated that we should take into account how people use and consume specific types of

food in establishing an upper limit, such as whether the food is a snack, an ingredient, or a center-of-plate food in a main meal, and whether a person is likely to eat more than two servings of food at one time. Another comment suggested that we reanalyze the data to provide category-specific RACC upper thresholds for dual-column labeling.

A few comments stated that we should only require dual-column labeling for product categories of food for which we have data indicating that a consumer can reasonably consume the entire package of a product between 200 percent and up to and including 400 percent of the RACC in one eating occasion. Other comments argued that an upper limit of 400 percent of the RACC would require dual-column labeling on foods that are not likely to be consumed in one eating occasion.

Several other comments requested that we require a lower upper limit for dual-column labeling generally. Some comments stated that dual-column labeling should only be required for packages up to 250 percent of the RACC, while other comments requested that dual-column labeling be required for packages up to 300 percent of the RACC.

We received comments that stated that by setting 400 percent as the upper limit for dual-column labeling, we would create the unintended consequence of establishing a dual-column labeling requirement for some products for which a 90th percentile of intake is much lower than 400 percent of the RACC, meaning that such products would be required to have dual-column labeling on package sizes for which consumption data shows that people do not reasonably consume the entire amount in one eating occasion. One example given in comments was for 100 percent fruit juices such as orange juice. Comments stated that the amount of fruit juice equal to 400 percent of the RACC would be 32 fl ozs, which is inconsistent with data showing that the amount of 100 percent fruit juice consumed at the 90th percentile is 219 percent of the RACC.

One comment noted that, based on NHANES 2003-2006 data, the 75th percentile of 100 percent orange juice consumption by adults is 8.8 fl ozs per day (Ref. 20) and for children age 2 to 18 years is 12.5 fl ozs per day (Ref. 21). Comments argued that requiring a dual-column label on a 32-oz container of orange juice does not represent the amount consumed by the majority of individuals.

Other examples given in comments of products for which a 90th percentile of intake is lower than 400 percent of the RACC were fluid milk and cottage cheese. Comments noted that the intake at the 90th percentile is 205 percent of the RACC for cottage cheese (226 g or 1 cup) and 181 percent of the RACC for milk (444 g or 14.5 fl oz). Some comments stated that a quart of fluid milk and a 16-oz container of cottage cheese are both at 400 percent of the RACC and would be required to have a dual-column label. Comments stated that labeling these two product packaging sizes with dual-column labels is inconsistent with how they are consumed.

Yet another example given in a comment of a product for which the 90th percentile of intake is lower than 400 percent of the RACC was frozen waffles. The comment described a 12.3 oz 8-pack of waffles where two waffles equal a serving based on the 85 g RACC. The comment stated that an 8-pack of waffles would be required to have a dual-column label listing nutrition information per two-waffle serving and per container. The comment stated that the 90th percentile intake for waffles is 168 percent of the RACC (about 3 waffles) and that it is difficult to imagine a consumer eating 8 waffles on one eating occasion.

Other comments asserted the following additional types of foods have consumption amounts at the 90th percentile that are less than 400 percent of the RACC and therefore are not appropriate for dual-column labeling: beverage product categories, frozen potato products, side dishes, natural cheese in 3.5 oz packages, sausage, nuts, frozen vegetables, frozen oatmeal,

frozen pizza, frozen entrées, canned beans, canned vegetables, canned fruits, 100 percent fruit juices, veggie “burger” patties, and cereal bars.

A few comments stated that they reviewed our data used to support the decision to use an upper limit of up to and including 400 percent of the RACC and found that in 84 percent of the food categories reviewed, average consumption was 299 percent or less of the RACC, and in 68 percent of categories, average consumption was 250 percent or less of the RACC. These comments stated that only a small number of product categories had consumption greater than 300 percent of the RACC, and those categories, which included wine coolers, fluid cream, lemon and lime juice, horseradish, and mustard, are not commonly consumed categories that should drive labeling changes.

Several comments argued that the 90th percentile was too high of an upper limit to be considered as a reasonably consumed amount and that the basis for our picking this value was unclear. One comment further requested that we provide information about the statistical distribution of these ratios to justify our cutoff of 400 percent. Other comments asserted that our decision to establish 400 percent of the RACC as the cutoff for dual-column labeling is arbitrary, incongruous with most common eating patterns, and could result in consumer confusion and needless changes for food manufacturers. Another comment suggested that we use the proposed RACCs, instead of RACCs from 1993, as the basis to compare to 90th percentile of intake.

(Response 19) In the preamble of the proposed rule (79 FR 11989 at 12003), we stated that our review of the intake distribution per eating occasion for each product showed that for almost all products, regardless of the amount of the RACC, the ratio of the intake at the 90th percentile level to the RACC was 400 percent or less. Use of the 90th percentile of intake distribution allows us to capture the substantial majority of consumption amounts per eating

occasion (i.e., 90 percent) for the U.S. population, but this level is not so high as to impose dual-column labeling requirements on most package sizes for which consumption data shows that people do not reasonably consume the entire amount in one sitting.

As noted previously, the purpose of dual-column labeling is to provide nutrition information for multiple ways in which people are likely to consume a product. Consumption data show that while some people eat certain products in a single eating occasion, others eat the product over time or share it. Dual-column labeling provides nutrition information for all of these scenarios. To the extent that comments suggested that dual-column labeling requirements generally would require needless changes to food labeling for manufacturers to comply with the dual-column labeling requirement and that the requirements may result in consumer confusion, we disagree. Dual-column labeling requirements are not intended to be limited to the single most common consumption pattern for a particular product. When determining the criteria for dual-column labeling, we therefore looked at data that shows how the product is consumed in 90 percent of eating occasions, to ensure that the requirements would encompass the distinct ways such products could reasonably be consumed. In the proposed rule we determined that dual-column labeling for products with 400 percent or less of the RACC would capture the most frequent consumption habits for almost all product categories.

We disagree with comments stating that the upper limit for dual-column labeling should be 250 percent. Eighteen percent of products have 90th percentile of consumption between 250 percent and 300 percent of the RACC based on the 1993 RACCs and the proposed RACCs, meaning that establishing an upper limit of 250 percent would eliminate from dual-column labeling requirements a significant proportion of products which data show are reasonably likely to be consumed in a single eating occasion.

In light of information provided in comments, we examined which food products have consumption levels at the 90th percentile between 300 percent and 400 percent of the 1993 RACCs and the proposed RACCs. Our analysis was consistent with those of comments that suggested that a substantial majority of food products (i.e., more than 90 percent) have consumption levels that are 300 percent or less of the RACC at the 90th percentile (Ref.16). We agree with comments to the extent they state that in the substantial majority of the food categories the average consumption was 300 percent or less of the RACC at the 90th percentile and that only a small number of product categories had consumption greater than 300 percent of the RACC at the 90th percentile. We also agree with comments that stated that setting an upper limit for dual-column labeling at 400 percent of the RACC could have the unintended consequence of requiring dual-column labels on packages for which data shows people do not reasonably consume in a single eating occasion, such as a quart of milk, a 32 fl oz bottle of juice, or a 12.3 oz 8-pack of waffles where two waffles equal a serving based on the 85 g RACC.

In consideration of the information provided in comments and further evaluation of relevant consumption data compared with the proposed RACCs, we are lowering the upper limit of dual-column labeling from 400 percent to 300 percent of the RACC. Providing an upper limit at 300 percent of the RACC would ensure that dual-column labeling captures 90 percent of the consumption habits for about 91 percent of food products and limit the possibility that dual-column labeling will be required for package sizes that are not likely to be consumed in a single eating occasion. As a result of our decision to lower the upper limit for dual-column labeling from 400 percent to 300 percent, certain products about which comments expressed specific concerns--such as a quart of milk, a 32 fl oz container of juice, a 16- oz container of cottage

cheese, and a package of waffles containing 4 servings--would not be required to have a dual-column label.

In response to those comments that suggested that we consider the type of product at issue in establishing an upper limit, we decline to apply different upper thresholds for dual-column labeling or to require dual-column labeling only for specific product categories. The use of a uniform upper criterion for all product categories will ensure that consumers are able to compare nutrition information across various product types that are packaged in the sizes that we have determined are reasonably likely to be consumed at one eating occasion or shared with others. For the same reason, we disagree with those comments that suggested that dual-column labeling is not appropriate for certain types of foods and decline to limit the dual-column labeling requirement to certain types of foods.

In response to the comment that recommended that we use the proposed RACCs, instead of RACCs from 1993, as the basis to compare to the 90th percentile of intake, this final rule relies upon both 2003-2008 consumption data and the 1993 RACCs as a basis to determine the 90th percentile of intake when determining an upper threshold for dual-column labeling. While the proposed rule used the 1993 RACCs as the basis to compare to the 90th percentile of intake, we agree that comparison to the proposed RACCs provides useful information. We have now reviewed the 90th percentile of intake for the proposed RACCs that we are finalizing with this rule. A review of this information shows that almost all of the proposed product categories have a 90th percentile of consumption that is less than 300 percent of the RACC. This information is included as a reference to this rule (Ref. 22).

(Comment 20) We received a few comments that stated that dual-column labeling should be voluntary instead of mandatory. Other comments suggested that all packages containing 200

percent or more of the RACC that can be reasonably consumed in a single eating occasion should be labeled as a single serving instead of using dual-column labeling.

(Response 20) We disagree with comments that state that dual-column labeling under § 101.9(b)(12) should be voluntary. As discussed previously in section III.C., we consider the benefits of dual-column labeling to the consumer--in particular, ensuring greater consumer understanding of the package's contents--to be significant enough to require dual-column labeling for products in containers that meet the criteria for dual-column labeling. As discussed in response to comment 8, to address the comment that suggested that we require mandatory listing as a single serving for packages over 200 percent of the RACC that can be reasonably consumed in a single eating occasion in place of dual-column labeling, the purpose of dual-column labeling is to provide label information for products that may be consumed in a single eating occasion, but can also be shared or eaten in multiple eating occasions. If these products are labeled as single-serving containers, then they would not provide nutrition information for all three of these scenarios. Additionally, as explained in detail previously in section II.B., under section 403(q)(1)(A)(i) of the FD&C Act, "serving size" means the amount customarily consumed. The RACCs we have established are reference amounts of food that are customarily consumed per eating occasion. As such, we do not consider it appropriate to label foods containing 200 percent or more of the applicable RACC as single-serving containers because that would be twice the amount or more than we have determined is customarily consumed.

(Comment 21) Some comments asserted that a multiserving container would only require dual-column labeling if the individual units contained at least 200 percent and up to and including 400 percent of the RACC, and argued that the relevant factor in establishing whether dual-column labeling is required is not the size of the entire multiserving container, but the size

of each individually packaged unit. Therefore, the comments concluded that the proposed dual-column labeling in § 101.9(b)(2)(i)(D) and (b)(12)(i) would be required if a unit in the multiserving container weighs at least 200 percent and up to and including 400 percent of the applicable reference amount. A few comments noted that for a multiserving container, the consumer must in some cases unwrap each unit, and thus would know how many units he or she has eaten. According to these comments, the number of those individual units should represent the number of servings in the multiserving container.

Several comments requested that we clarify that the proposed changes in § 101.9(b)(2)(i)(D) and (12)(i) are not intended to require dual-column labeling on a multiserving retail container comprised of individual discrete units, when the multiserving retail container as a whole contains at least 200 percent and up to and including 400 percent of the RACC. Examples provided in comments of these types of packaging configurations were a four-pack of individually packaged 6 oz yogurt containers, individually wrapped cupcakes, muffins, and breakfast pastries. In the examples given, the multiserving retail container contained at least 200 percent and up to and including 400 percent of the RACC, but each of the individual discrete units contained less than 200 percent of the RACC.

One comment noted we typically do not use the phrase “packaged and sold individually” to describe multipack products and, citing to § 101.9(b)(2)(i), stated that we instead refer to the multipack containers as “packages containing several individual single-serving containers” and that we refer to units as “individually packaged products within a multiserving package.” The comment asked us to clarify that the proposed criteria for mandatory dual-column labeling applies only to those individual units that have between 200 and 400 percent of the RACC and not to the multipack container when the weight of the multipack is between 200 and 400 percent

of the RACC. The comment stated that in the proposed rule we specifically identify a “grab-size bags of chips” as an example of a product that would be subject to dual-column labeling if it contains 200 percent to 400 percent of the applicable RACC, even though the comment considered chips to appear to be a non-discrete bulk product.

(Response 21) Dual-column labeling with nutrition information listed per serving and per unit is required for each product in discrete units in multiserving containers when the unit weighs at least 200 percent and up to and including 300 percent of the applicable RACC. Section 101.9(b)(2)(i) provides, in part, the requirements for serving sizes for products in discrete units (e.g., muffins, sliced products, such as sliced bread, or individually packaged products within a multiserving package). Under proposed § 101.9(b)(2)(i)(D), if the individual unit within a multiserving container weighs at least 200 percent and up to and including 400 percent of the applicable RACC, the manufacturer would need to provide an additional column that lists the quantitative amounts and percent DVs for the individual unit, as well as a column listing the quantitative amounts and percent DVs for a serving that is less than the unit (i.e., the serving size derived from the RACC). The first column would be based on the serving size for the product, and the second column would be based on the individual unit. We are amending § 101.9(b)(2)(i)(D) in this final rule to apply to individual units within a multiserving container that weigh at least 200 percent and up to and including 300 percent of the applicable RACC. The reason for the change from 400 percent of the RACC as the upper limit to 300 percent of the RACC as the upper limit is discussed in section III.B. We have also modified the language for clarity.

Under the proposed rule, dual-column labeling would be required on a multiserving retail container comprised of individual discrete units, when the multiserving retail container as a

whole contains at least 200 percent and up to and including 400 percent of the RACC. As explained in response to comment 9, a product that is packaged and sold individually (i.e., a container that bears a Nutrition Facts panel) that is comprised of individual discrete units and that as a whole contains at least 200 percent and up to and including 300 percent of the RACC would be subject to the dual-column labeling requirements under § 101.9(b)(12)(i) in this final rule, unless an exemption applies. If, for example, the product at issue is a box containing two individually bottled, 16 oz sodas, and if the box, and not the bottles, were to display the Nutrition Facts label, the multipack container would be required to bear dual-column labeling because the multipack would be packaged and sold individually and would contain at least 200 percent and up to and including 300 percent of the RACC. In contrast, if the product at issue is encased in a clear plastic wrapper and includes two individually bottled, 16 oz sodas for which each bottle is labeled with a Nutrition Facts panel that is visible at the point of sale, the outside wrapper would not be required to bear dual-column labeling even though the combined weight of all bottles would be at least 200 percent and up to and including 300 percent of the RACC. We note that § 101.9(b)(12)(i) pertains to products that are packaged and sold individually and contain at least 200 and up to and including 300 percent of the RACC, regardless of whether the product is in discrete units.

With respect to the comment's request for clarification about whether a "grab bag" of chips would be subject to the dual-column labeling requirements, we note that if such a bag of chips were to bear a Nutrition Facts panel and contain at least 200 percent and up to and including 300 percent of the RACC, it would be subject to the dual-column labeling requirements unless an exemption applied. Whether a product contains discrete units or non-discrete bulk food, dual-column labeling is required if the criteria for such labeling is met, and if

no exemptions apply. Section 101.9(b)(2)(i)(D) explains when a second column of nutrition information that describes the nutrient content per unit is required, and § 101.9(b)(12)(i) explains when a second column of nutrition information that describes the nutrient content per container is required.

(Comment 22) One comment noted that our rounding rule requirements may present inherent problems because the requirements may cause quantitative amounts and percent DVs to look inconsistent when displayed in a dual-column format per serving and per container. The comment suggested that this result may not satisfy the requirements of section 2(b)(1)(A) of the NLEA if dual-column labeling does not convey information in a manner that “enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.” To demonstrate the potential inconsistency, the comment provided an example of a Nutrition Facts label of two different flavors of candy bars which presented nutrition information per two pieces and per one piece. The comment noted that the calories from fat for two pieces is 111.0 g (actual) but is rounded to 110 g using our rounding rules, while the calories from fat for 1 piece is 55.5 g (actual), but rounded to 60 g using our rounding rules. The comment noted that this discrepancy may cause consumer confusion since if the serving size were halved they would expect the declaration of “Calories from fat” to be 55 g. The example provided in the comment also demonstrated inconsistencies in the values provided for total fat, sodium, and protein due to our rounding rules. The comment suggested that we permit the use of a footnote such as “Columns may not add due to rounding” when such inconsistencies exist.

(Response 22) We acknowledge that the use of dual-column labeling per serving and per container could, under certain conditions, cause apparent discrepancies in the nutrition values

between the two columns. The discrepancies would result from mathematical rounding procedures and our requirements for the increments in which nutrition values are declared in the Nutrition Facts label under § 101.9(c). We recognize that consumers viewing nutrition information per serving and per container may expect the nutrition values per container to result from multiplying the number of nutrients per serving by the number of servings per container, and that the numbers that may result under existing regulations may not reflect this expectation in all cases. However, under the preexisting nutrition labeling regulations, consumers may have already seen such rounding issues in the labeling of products in discrete units in a multiserving container that are more than 1 unit (§ 101.9(b)(10)(ii)).

While we acknowledge that in some instances apparent discrepancies may occur, we are not proposing to change our requirements for the increments in which nutrition values are declared in the Nutrition Facts label (§ 101.9(c)). Changes to this regulation, such as a requirement that the per-container information be provided by multiplying the nutrients per serving by the number of servings, would likely result in the need to round the information twice. This could result in a requirement to provide nutrition information per container in a way that does not accurately reflect the amount of nutrients in the product. We consider this result to be more problematic than any apparent discrepancies that may result from existing rounding requirements. However, we will monitor this situation as more products are introduced into the marketplace with dual-column labeling per serving and per container.

We disagree with the comment suggesting the need for a footnote such as “Columns may not add due to rounding.” The presence of a footnote will require additional space, and we do not believe at this time that any apparent rounding discrepancies are significant enough as to warrant a requirement to include such a footnote or to permit the use of such a footnote

voluntarily. We do, however, plan to include information about potential rounding discrepancies as part of our planned nutrition education efforts to clarify why the per-serving and per-container nutrition values appearing on dual-column labels may not appear consistent. We also note that, while no such footnote as requested in this comment can be added to the Nutrition Facts label, manufacturers can voluntarily include a truthful and not misleading statement explaining how rounding effects dual-column labeling elsewhere on the product label.

3. Exemptions from Dual-Column Labeling

(Comment 23) One comment asserted that we acted arbitrarily in proposing to exempt the following types of products from the dual-column labeling requirement because we determined that labeling of such products with nutrition information based on the entire container would not be consistent with how these products are typically consumed: Bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), bulk products traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes.

(Response 24) After further consideration of this exemption, and as explained in response to comment 19, the use of a uniform upper criterion for all product categories will ensure that consumers are able to compare nutrition information across various product types that are packaged in the sizes that we have determined are reasonably likely to be consumed at one eating occasion or shared with others. We have no consumption data showing that it is reasonably likely that bulk products are consumed differently from non-bulk products. Therefore, we are not finalizing the exemption for bulk products that are used primarily as ingredients, bulk products traditionally used for multipurposes, and multipurpose baking mixes as proposed in § 101.9(b)(12)(i)(B).

(Comment 24) We received comments relating to proposed exemptions from dual-column labeling requirements for products that require further preparation, such as macaroni and cheese kits, pancake mixes, pasta products, and common combinations of food (e.g., cereal and milk) that contain at least 200 percent and up to and including 400 percent of the applicable RACC. Comments we received regarding this exemption were generally supportive of the exemption. A few comments, however, stated that instead of allowing products to be exempt from dual-column labeling, we should instead require dual-column labeling per serving and per container for the as-prepared form of the product and eliminate the as-purchased information altogether.

We received a few comments requesting that we allow an exemption for any product that provides voluntary dual-column labeling as allowed under the preexisting regulations in § 101.9(b)(10)(i) to (iii). Another comment requested that we provide exemptions from dual-column labeling under § 101.9(e) not only for products that provide an additional column of information for two or more forms of the same food “as purchased” and “as prepared” and for common combinations of food, but also when nutrition information is provided for two or more groups for which Reference Daily Intakes (RDI’s) are established (e.g., both infants and children less than 4 years of age) or when nutrition information is provided in different units (e.g., slices of bread or per 100 g).

(Response 24) We agree, in part, with comments that support allowing an exemption to the dual-column labeling requirements if the voluntary provisions provided for in § 101.9(b)(10) are used. The exemptions under § 101.9(b)(10) are for products that provide another column of figures that may be used to declare the nutrient and food component information per 100 g or 100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased (§ 101.9(b)(10)(i)); per one

unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit (§ 101.9(b)(10)(ii)); and per cup popped for popcorn in a multiserving container (§ 101.9(b)(10)(iii)). We agree that providing voluntary dual-column labeling per unit if the serving size of a product in discrete units in a multiserving container is more than 1 unit would provide useful information to those that consume one unit, and therefore are permitting the use of such a second column of information in lieu of a second column that provides per-container information. We also agree that providing voluntary nutrition information per cup of popped popcorn per serving in a multiserving container (§ 101.9(b)(10)(iii)) in an as-consumed form will be more beneficial to consumers than having nutrition information for the “as purchased” form on both a per-serving and per-container basis. As explained further in comment 25, while we recognize that popcorn is not consumed in the as-purchased form, the as-purchased nutrition information is still needed. Therefore, we are permitting the label of such products to contain a second column of information for the popped form, in lieu of a second column that provides per-container information.

As noted in the serving size proposed rule, we tentatively concluded that it would be helpful to consumers to have access to nutrition information based on the prepared form of the product in addition to the “as purchased” form of the product (79 FR 11989 at 12004). We are reaffirming that conclusion in this final rule. The “as prepared” information on labels indicates the nutritional information per serving if a package is prepared according to package directions, which may require the use of additional ingredients. We disagree, however, with those comments that stated we should require dual-column labeling to be done only based on the as-prepared form, per serving and per package. If a consumer does not use the stated directions or uses substitute ingredients, then the information in the as-prepared portion of the label would not

be accurate. Therefore it is important that each product include nutrition information for the product as packaged and not just the product as it is prepared. We also noted in the proposed rule that if products that voluntarily included one column of nutrition information for the prepared form of the food per serving and met the requirements for dual-column labeling, they would have to include at least three columns of nutrition information unless the products were subject to an exemption (79 FR 11989 at 12004). We are reaffirming our conclusion from the proposed rule that nutrition information based on the entire container of the unprepared food may be less meaningful to consumers than information based on a serving of the prepared form of the food and are therefore finalizing an exemption from the dual-column labeling requirements in § 101.9(b)(12)(i)(C) for those products that voluntarily include a second column of nutrition labeling for the as-prepared form of the food per serving.

We do not agree with comments that requested an exemption for products that provide an additional column that declares the nutrition information per 100 g or 100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased. In the introduction to section III.C., we discussed our basis for concluding that per-container information helps certain consumers recognize nutrient amounts per package and that the consumption data shows that consumers are reasonably likely to consume a full package containing at least 200 percent and up to an including 300 percent of the RACC. In contrast, consumers may not be able to readily measure 100 g or 100 mL amounts, so the information may not be useful to them. Because we have determined that nutrition information per serving and per container is more likely to be useful to consumers, and therefore is more important than voluntary nutrition information given in metric or common household measurements (oz) for the food in the as-purchased form per serving, we decline to establish an exemption when a second column of nutrition information is provided per 100 g or

100 mL, or per 1 oz or 1 fl oz of the food as packaged or purchased. While nutrition information per 100 g or 100 mL cannot be listed in lieu of the information required under § 101.9(b)(2)(i)(D) and (b)(12)(i), § 101.9(b)(10)(i) allows the manufacturer to provide this information in an additional column (e.g., a third column) on a voluntary basis.

We agree with the comment that requested that we expand the exemptions from dual-column labeling to include products that voluntarily provide a second column of nutrition information for two or more groups for which RDIs are established (e.g., both infants and children less than 4 years of age). Providing voluntary nutrition information for two or more groups for which RDIs are established provides useful information for the different populations that may consume the food product. Providing nutrition information for two subpopulations, such as infants 7 to 12 months old and children aged 1 through 3, will provide beneficial information to purchasers of these products. Such nutrition information will provide meaningful information about foods that are typically consumed in distinct amounts by distinct subpopulations. This exemption has been added to § 101.9(b)(12)(i)(C) in this final rule.

We note that in this final rule we are also providing an exemption from dual-column labeling for varied-weight products covered under § 101.9(b)(8)(iii), for which dual-column labeling would be less practical given the variation in product sizes.

(Comment 25) We received several comments questioning why popped popcorn needed a dual-column label listing nutrition information with one column for “as purchased” unpopped popcorn and another column for “as prepared popped” popcorn. The comments noted that no one consumed raw popcorn and that the “as purchased” popcorn information is unnecessary. One comment requested that the RACC for popcorn be changed from 30 g unpopped (raw) to 30 g as consumed because variations in hybrids, popping volume and other ingredients can

significantly alter the amount of kernels in a single serving based on the household measure (typically tablespoons) for the finished product. The comment requested that we change the current declaration for uncooked popcorn to reflect how the product is actually consumed by the consumer versus “as packaged.” The comment noted that providing the nutrition information about unpopped popcorn could be confusing and misleading to the consumer and that no other snack has its raw form as the basis for its nutritional information.

(Response 25) We decline to amend the way in which nutrition information is required to be presented for popcorn, which is that popcorn must provide nutrition information on the “as packaged” or “purchased” form of the food (i.e., unpopped form), as described in § 101.9(b)(9). We disagree with the assertion that providing nutrition information about popcorn in the “as packaged” form is unnecessary and that the “as packaged” nutrition information should not be required to appear on the product label if the “as prepared” information is provided. The “as prepared” information on labels indicates whether a package is prepared according to package directions, which may require the use of additional ingredients. If a consumer does not use the stated directions or uses substitute ingredients, then the information in the as-prepared portion of the label would not be accurate. Therefore it is important that each product include nutrition information for the product as packaged and not just the product as it is prepared. We note, however, that although it is not permitted for popcorn to provide a single-column label containing only as-purchased information, our regulations provide that popcorn products can provide a second column of nutrition information “per cup popped” for popcorn in a multiserving container (§ 101.9(b)(10)(iii)); many popcorn products already voluntarily have a second column of nutrition information per serving for the “as popped” form. We are not changing this voluntary provision. In addition, we have provided an exemption from the dual-

column labeling provisions in § 101.9(b)(12)(i) for products that require further preparation, which would apply to popcorn products that contain at least 200 percent and up to and including 300 percent of the RACC and voluntarily provide an additional column of nutrition information on the “as popped” form.

With regard to the comment that stated that listing popcorn on the as-purchased basis would be confusing to consumers, the comment did not explain the basis on which the as-purchased information would be confusing or misleading, and we do not agree that such information would be confusing or misleading. With regard to the assertion that no other snack has its raw form as the basis for its nutritional information, we disagree. All products are required to provide nutritional information for the as-packaged form, so any products that are packaged in their raw form are required to provide nutritional information for the raw form.

We also decline the request to change the RACC of popcorn to 30 g popped per serving “as consumed.” In the preamble of the 1993 serving size final rule (58 FR 2229 at 2265 to 2266), we discussed comments that requested that popcorn be able to use a volume-based rather than a weight-based reference amount. We declined to follow the recommendation from those comments because we determined that there is no well-established standard procedure for determining the weight equivalents of the household measures. This is still true today. However, for the benefit of those consumers who consume popcorn on a volume basis, we permit the use of a voluntary dual-column label with the second column of nutrition information being based on a per cup popped basis. Therefore we decline to change the popcorn RACC to an as-consumed amount.

(Comment 26) A few comments requested clarity on whether raw fruits and vegetables would be exempt from dual-column labeling when nutrition labeling is voluntarily provided or

when claims are made for such products. An example used in the comment was a medium avocado that has a proposed RACC of 50 g, or about $\frac{1}{3}$ of the avocado. According to the comment, the entire avocado would be about 150 g and would require dual-column labeling if nutrition labeling is voluntarily provided or if claims are made for such product in labeling or advertising. Another comment requested that we exempt all fruits and vegetables without added sugar, salt, or fat from dual-column labeling.

(Response 26) Under § 101.9(j)(10), raw fruits, vegetables, and fish are exempt from mandatory nutrition labeling, contingent on the food bearing no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. The labeling of such products is generally done on a voluntary basis, with guidelines for such labeling set forth under § 101.45. Under § 101.45(a)(3)(i), such products are not required to provide information about the number of servings per container. Because the number of servings per container would vary from container to container, we do not expect those selling raw fruit, vegetables, and fish to be able to provide information about the number of servings for an individual container and therefore do not expect them to be able to provide a second column of information with nutrition information per container. Additionally, when voluntary nutrition information for raw fruits, vegetables, and seafood is provided under § 101.45(a)(1), it should be displayed at the point of purchase by an appropriate means such as by a label affixed to the food or through labeling including shelf labels, signs, posters, brochures, notebooks, or leaflets that are readily available and in close proximity to the foods. The nutrition labeling information that is voluntarily provided may also be supplemented by a video, live demonstration, or other media. Because no information about the number of servings per container is generally required in voluntary labeling, and because the nutrition labeling for such products is often provided in a non-

standardized manner, we agree that such products should be exempt from dual-column labeling. Therefore, we will amend § 101.9(b)(12)(i)(B) to provide that raw fruits, vegetables, and seafood will be exempted from the dual-column labeling requirements, regardless of whether voluntary nutrition information is provided for the product, either in labeling or in advertising, or whether nutrition claims are made for the product.

We decline to exempt canned or frozen fruits and vegetables without added sugar, salt, or fat from the dual-column labeling requirements. Unlike raw fruits and vegetables, the presentation of nutrition information, including the number of servings per container, has been established in § 101.9 for canned or frozen fruits and vegetables, regardless of whether they contain added sugar, salt, or fat. It is therefore less difficult for canned or frozen fruits and vegetables to provide dual-column labeling when the applicable dual-column labeling requirements would apply.

(Comment 27) One comment requested that bottled water products be exempt from the requirements of dual-column labeling. Other comments questioned the benefits to consumers of requiring dual-column labeling for bottled water products when most of the values in the two columns would be zero. The comments further noted that many bottled water products are already exempt from the nutrition labeling requirements under § 101.9(j)(4) because they contain insignificant amounts of all nutrients required to be declared in the nutrition facts label, and requested that we amend § 101.9(j)(4) to clarify that such products would be exempt. The comments noted that under the proposed rule, the RACC for bottled water products would increase from 240 mL (8 oz) to 360 mL (12 oz) and that this increase in the RACC would mean that the sodium content per RACC in some bottled water products would exceed the current 5 mg per serving threshold, below which the amount of sodium would be considered

insignificant. Therefore, the comment requested that we revise the definition of an insignificant amount in § 101.9(j)(4) to be an “amount that allows a declaration of zero in nutrition labeling, except that for sodium, it shall be an amount that exceeds a declaration of zero percent of the daily value, and except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of less than 1 gram.”

(Response 27) We decline to establish an exemption to the dual-column requirements in this final rule for bottled water products. We also decline to amend § 101.9(j)(4) at this time as suggested by the comment. We intend to consider the applicability of an exemption from nutrition labeling requirements in a future rulemaking with respect to certain products. Until such time as we have had the opportunity to consider such matters further, we intend to consider the exercise of enforcement discretion with respect to mandatory nutrition labeling on bottled water products and other products that would have been exempt under § 101.9(j)(4) prior to the effective date of this rule and the Nutrition Facts final rule.

(Comment 28) One comment stated that providing nutrition information on a “per container” basis for a consumer who intends to eat some now and some later, or for a consumer who will share the container with others, is not useful information. The comment asserted that consumers have all the nutrition information they need to make food choices in the “per serving” declaration.

(Response 28) To the extent that this comment asserts dual-column labeling does not provide additional, useful information to consumers, we disagree. The intent of dual-column labeling is to provide nutrition information for products that may be consumed by one consumer in a single eating occasion, over several eating occasions, or shared among multiple consumers. A dual-column nutrition label provides easy-to-interpret nutrition information for a consumer

who may eat the contents of a package in one sitting. Dual-column labeling serves as a contextual cue that there is more than one serving in a package and helps consumers to easily figure out how much is in the entire container.

(Comment 29) We received a comment requesting that we exempt foods specifically represented or marketed to infants or children 1 to 3 years of age. The comments stated that presenting the nutrition information for the entire container could inappropriately communicate that a young child could reasonably consume the entire contents of a container. The comment used juice as an example with an RACC of 4 fl oz and noted that a 16 fl oz juice container marketed for children 1 to 3 years would need to include a column for the entire container under the proposed rule. The comment stated that such labeling could indicate to consumers that juice is recommended to be consumed in greater quantities and would conflict with portion guidance provided to parents regarding limiting juice consumption to no more than 4 fl oz per day.

(Response 29) We decline to exempt foods specifically represented or marketed to infants or children 1 to 3 years of age from mandatory dual-column labeling. The purpose of dual-column labeling is to provide nutrition information for those who consume the entire container in one eating occasion, as well as those who consume the container over multiple eating occasions or share the container with others, and to help consumers more easily understand the contents of a particular package both on a per-serving and per-container basis. In terms of consumers misconstruing the serving size as a recommended amount of food, we noted previously in section III.A. that we will engage in consumer education to help clarify the meaning of the serving size. We note that since we have lowered the upper level of dual-column labeling to 300 percent of the RACC, the example stated in the comment would not occur.

4. Research and Consumer Understanding of Dual-Column Labeling

(Comment 30) We received comments that questioned the research cited in the proposed rule in support of dual-column labeling (Ref. 14). Some comments stated that consumer research should include an evaluation of whether consumers would use the dual-column information to modify dietary choices when provided. Comments stated that the limited amount of research on dual-column labeling was not enough to require mandatory dual-column labeling for all products.

Various comments questioned the format of the dual-column labels used in the studies. Some comments pointed out that both studies cited in the proposed rule evaluated the current label format with dual columns, rather than the proposed new label format with dual columns. The comments stated that with the proposed label formats, dual-column labeling is not needed because the values consumers need to determine the total calories in the container would already be available to the consumer.

Some comments questioned the results of the study conducted by Antonuk and Block that was cited in the proposed rule. These comments stated that the results of the study are not generalizable because the study was conducted with undergraduate students in a classroom setting. Some comments stated that the study only used labels for snack food products and that the results should not be used to evaluate the effects of dual-column labels on other product categories. Other comments questioned the different results for dieters versus nondieters.

(Response 30) We disagree with the comments that suggest that in order to support the requirement for dual-column labeling, research must demonstrate that dual-column information modifies dietary choices. As noted previously, the purpose of dual-column labeling is to provide nutrition information for multiple ways that people are likely to consume a product that contains

at least 200 percent and up to and including 300 percent of the RACC. Consumption data shows that while some people eat such products in a single eating occasion, others eat the product over time or share it. Dual-column labeling provides nutrition information for all of these scenarios.

The comment incorrectly asserts that the studies on which we relied in the proposed rule used only labels for snack food products. The labels tested in the Lando and Lo study (Ref. 15), which were also cited in the proposed rule, included sample Nutrition Facts labels for frozen meals, which are not considered “snack foods.” Additionally, since the publication of the proposed rule, we have conducted further research on dual-column labeling. The new study has tested dual-column labels using the proposed label formats, recruited participants from a Web-based panel of English speaking adults, and examined multiple food products (Ref. 19). The results from the research showed that dual-column labeling significantly improved respondents’ ability to identify the amount of nutrients in the entire container of a two-serving package compared to both a single-column label and a dual-calorie label. Based on this research, as well as the research cited in the proposed rule, we conclude that consumers can more easily and more accurately comprehend the nutrient contents of an entire package when dual-column labeling is available, and we disagree with those comments that stated that dual-column labeling is not needed.

With respect to comments that questioned whether the results of the study conducted by Antonuk and Block that was cited in the proposed rule are generalizable, we acknowledge the study’s limitations as noted in the comments. In spite of the fact that the results are not generalizable, we note that the study suggests that, at least under circumstances that are the same as or similar to those in the study, it is possible that some consumers may behave like the study participants. The finding of this study is consistent with other research that we are aware of;

therefore, we are convinced by the totality of the research that dual-column labeling can help consumers better understand the nutrition contents of containers of certain sizes and assist them in maintaining healthy dietary practices.

(Comment 31) Several comments stated that providing nutrition information for the entire package will cause consumer confusion and increase consumption. Some comments argued that consumers would interpret the nutrition information for the entire package to be a recommended amount to eat and consume more of the product than they would have likely consumed without the dual-column label.

(Response 31) These comments did not provide data or other information in support of their assertions. Based on a review of available information, we have seen no indication that dual-column labeling may be confusing to consumers or that dual-column labeling would imply that consumers should eat more of an item.

(Comment 32) We received a comment that included results of a study conducted by the commenter on the proposed Nutrition Facts label formats. The study was designed to investigate the extent to which consumers are able to quickly notice and understand label information, as they would during grocery shopping. The study compared consumer reactions to FDA's current and proposed versions of four different Nutrition Facts label formats, each portraying a different food product, so that a total of eight different labels were examined. The current and proposed label formats, and the foods depicted, were standard format for single-serve yogurt; tabular format for frozen vegetables; dual-column label for breakfast cereal (per serving and with ½ cup skim milk); and a dual-column label for a multiserving snack mix package (per serving and per container). Each participant viewed and reacted to one label.

According to the comment, the study found that, in general, the proposed formats performed no better than the current formats in conveying nutrition information to respondents, but the results varied according to the information on the labels being considered. With respect to the dual-column labels, the comment stated that no differences were found in the “quick readability” or in participants’ comprehension of the serving size or calories information between the current and proposed formats of both the snack mix and cereal products. The authors also asserted that participant understanding of nutrition information was better with the proposed dual-column cereal label but not with the proposed dual-column snack mix product. Further, the authors stated that respondents found the information for vitamins and minerals to be less confusing on the snack mix label that displayed both the percent DV and the absolute amounts per serving and per container (i.e., the proposed dual-column format) than on the label showing this information only per serving (i.e., the current single-column format). However, according to the study authors, when asked an open-ended question about items that were easy to understand or confusing on the label, a larger percentage of respondents indicated that it was more difficult to understand the percent DV information on the proposed snack mix label than on the current version of this label. The comment stated that the result also suggest that respondents were less likely to initially notice the serving size information on the proposed labels for both the snack mix and cereal products compared to the current formats for these products. The authors postulated that these results were due to the complexity of the proposed dual-column label formats, and they recommended that FDA should not implement the proposed changes in format for the Nutrition Facts label because their study indicated that participants perceived few differences between the current and proposed label formats.

(Response 32) We have significant questions about the methodology and design of this study. Although we acknowledge that this study did not demonstrate a clear advantage to the proposed versus the current format under all experimental conditions, the results are difficult to interpret because a number of details were not provided. Among other things, the authors did not adequately describe the study's methodology, such as by explaining the demographic characteristics of the participants, the statistical methods that were used, how the participants were selected, how the study was administered, and why 90 percent confidence levels were chosen to indicate significant differences rather than the conventional 95 percent confidence interval. Further, the proposed snack mix label that was used in the study appeared to be inconsistent with the proposed requirements in how the "per serving" and "per container" values were listed for various nutrients. Although the label indicated "3½ servings per container," the amounts of some nutrients (e.g., calories, carbohydrates, sodium, protein) that were listed on the label suggested that there were 4 servings per container, and the amount of dietary fiber shown on the label indicated there were only 2½ servings per container. Because of these substantial questions about the sufficiency in the study design and the study's methodology, we are not persuaded by this comment.

As noted previously, recent NHANES data shows that consumers are reasonably likely to consume products containing at least 200 percent and up to and including 300 percent of the RACC in a single eating occasion. Our research demonstrates that some consumers may have difficulties determining nutrition information per container when a label declares the package contains more than one serving and is reasonably consumed in a single eating occasion. We are therefore finalizing dual-column labeling requirements in this rule to help consumers better

understand the nutrition contents of packaged foods containing at least 200 percent and up to and including 300 percent of the RACC.

5. Dual-Column Labeling Format

(Comment 33) We received several comments regarding the format of dual-column labels relating to whether per-container nutrition information should appear for all nutrients for which information is available on a per-serving basis, whether per-container nutrition information should be limited to calorie content, or whether per-container information should be limited to calories, saturated fat and sodium.

The comments were divided on whether we should require dual-column labeling with per-serving and per-container (or unit, as applicable) information for all nutrients or whether we should require only calorie information per serving and per container with the rest of the nutrition information listed in a single column. Only one comment requested that we consider using the option to provide nutrition information per serving and per container (or unit, as applicable) for calories, saturated fat and sodium only. Although comments were divided on which of the other two formats to use (i.e., per-container information for all nutrients versus per-container information for calories only), many comments stated that the decision on which dual-column label format to use should be based on consumer research on what information would be most useful to consumers in deciding the amount of a food or beverage to consume.

Comments that requested that we use dual-column labeling for all of the nutrition information per serving and per container stated this option would allow consumers to base decisions on the product's overall nutrient profile. A few comments stated that access to the full nutritional information for a serving as well as the entire container is necessary for consumers who are looking for specific nutrition information. The comments stated that individuals have

varying nutritional requirements and need to see dual-column nutrition information for all nutrients in order to maintain healthy dietary practices.

Comments that requested that we require dual-column labeling for calories only stated this approach would provide consumers with information they need to accurately identify the number of calories in a product, but would also save space and avoid cluttering the Nutrition Facts label. Comments argued that the issues we were looking to address with dual-column labeling would be alleviated through the proposed formatting changes and, specifically, the larger type size and prominence for calories and servings per container, as proposed in “Food Labeling: Revision of the Nutrition and Supplement Facts Label” (79 FR 11880, March 3, 2014). These comments asserted that our proposal to increase the prominence of calories and servings per container would give consumers the piece of information most relevant to a package that might be eaten by a single consumer during a single eating occasion, i.e., the calorie content of the entire container.

One comment stated that full dual-column labeling information is not needed because a consumer that chooses to eat two, three, or four servings of the product can easily calculate the quantity of calories and nutrients consumed through simple math. Another comment noted that in the study we conducted (Ref. 15), a label format with dual listings for calories only had the next highest level of accuracy (total correct) on the broad index of the nutrient content questions posed to study participants compared to the accuracy of the one serving, single-column format and two serving, dual-column formats (Ref. 15). Other comments said dual-column labeling for food packages that contain 200 percent and up to and including 400 percent of the RACC could actually decrease the utility of the Nutrition Facts label by cluttering the label and making it difficult for consumers to read. Another comment questioned whether requiring that information

per container be available for consumers so they don't have to do the math by multiplying the per serving values by the number of servings is justified in spite of the additional space this information will occupy. The comment stated that a dual-calorie label, which highlights the calories per serving and per container, is a better and more targeted use of limited label space than a dual-column label for all nutrients.

(Response 33) We agree with the comments that noted that dual-column labeling with information per package and per serving for all nutrients is most useful for consumers who are looking for specific nutrition information. The research cited in the proposed rule has shown that consumers better understand nutrition information when using a dual-column label that shows two columns of nutrition information, per serving and per container, as compared with a label that shows dual information for calories only. Further, because different consumers are interested in different nutrients when evaluating products, providing dual-column labeling for all nutrients would be helpful to more consumers. We are not aware of any studies that have evaluated a Nutrition Facts label with only dual-column information for calories, saturated fat, and sodium per serving and per container.

In response to those comments that requested that we base our decision on which label format to use on consumer research, it is in light of the research findings discussed in section III.C. and in comment 29, as well as the usefulness of full nutrition information for different types of consumers, that we are choosing the option for dual-column labeling per serving and per container (or unit, as applicable) for all nutrition information on the label.

In response to comments that stated that consumers do not need the additional information or that consumers can easily do the math to determine nutrition information per container, the research does not support this assertion. Studies have found that consumers are

able to most accurately determine the quantity of nutrients in specific foods when using labels that list full nutrition information for the entire package (Ref. 19). In addition, as discussed in the preamble to the proposed rule (79 FR 11989 at 11998), research suggests that many consumers do not correctly calculate nutrient amounts in food products by multiplying the nutrient amount by the number of servings per container (Refs. 23 and 24). One research study of 200 primary care patients found that many patients, especially those with lower literacy and numeracy skills, had trouble using food labels for performing certain tasks, especially those that involved calculations with serving size information (Ref. 24). Similar results were reported in the “Calories Count” report (Ref. 1).

We disagree that consumers do not need the additional information or that consumers can easily do the math to determine nutrition information per container. Our study with 160 consumers showed participants a pair of single-column Nutrition Facts labels, with one label showing a serving size of one and another label a serving size of two and asked them to identify which product contained fewer calories per container (Refs. 18 and 19). The proportion of participants who noticed the calorie declaration or the number of servings declaration did not vary between a single-column current format and a single-column proposed format (Refs. 18 and 19). Neither did the proportions of participants differ with regard to how many could identify which product contained fewer calories per container. The study also showed that while the majority of participants noticed the calorie disclosure, less than one third of the participants were able to identify whether the label with a serving size of one or the label with a serving size of two contained fewer calories per container. These results suggest that some consumers may not notice and use all the information available on a single-column, multiserving label that could reasonably be consumed in a single eating occasion and that some consumers may not accurately

use (e.g., as a result of mathematical errors) and correctly recognize a product's nutrient contents if a product contains more than one serving.

We do not agree with the comment that asserted that the proposed changes for increasing the prominence of calories and the serving size information will alleviate issues that we are seeking to address with dual-column labeling. In our study, the proportion of participants who saw the proposed format changes (i.e., increased prominence of calories and the serving size information) and did not notice the number of servings was not different from the proportion of participants who saw the preexisting format and did not notice the number of servings, even though calories and the number of servings were made more prominent on the proposed format (Ref. 18). We are also concerned about ensuring that consumers have access to per-container nutrition information for products that contain at least 200 percent and up to and including 300 percent of the RACC so consumers who eat the entire container in one eating occasion, over multiple eating occasions, or shared with others can accurately identify the information for the entire container.

To address the comment that stated that listing dual-column nutrition information for calories only is a better and more targeted use of limited label space than a dual-column label for all nutrients, we disagree. Findings from a study we conducted after the publication of the proposed rule found that participants were able to better identify total nutrients per container when using the full dual-column label, as compared with the dual-column label for calories only (Ref. 19). Providing dual-column labeling for the entire container gives consumers access to nutrient information for each specific nutrient on the Nutrition Facts label.

(Comment 34) One comment stated that, as grocery shelf space has become increasingly expensive, packages have become narrower and taller, ultimately increasing vertical space to

greater than 3 inches in height and making the back panel longer and thinner. The comment stated that, for these types of small or tall and narrow packages with seams down the back, it will be difficult, if not impossible, for manufacturers to fit a dual-column nutrition facts label, which is nearly twice as wide as the current single-column facts panel. The comment requested that we propose additional dual-column options for industry review that account for the constraints associated with different product formats and smaller package sizes.

(Response 34) We recognize the concerns expressed in this comment. Under proposed § 101.9(b)(12)(i)(A), which this rule finalizes without changes, the dual-column labeling requirements in proposed § 101.9(b)(12) would not apply to products that meet the requirements to present the Nutrition Facts label using the tabular format under current § 101.9(j)(13)(ii)(A)(1) or the linear format under current § 101.9(j)(13)(ii)(A)(2). If a product has limited space and uses a tabular or linear format as described in the regulations, it would not be required to use dual-column labeling. We also recognize that the shape of the container will play a role in the amount of space available to display the Nutrition Facts label and note that information related to placement of information on the information panel is described in § 101.2. An example of a dual-column label using the tabular display format in § 101.9(d)(11)(iii) is being published elsewhere in this issue of the Federal Register in the Nutrition Facts final rule.

D. Reference Amounts Customarily Consumed

We proposed to update, modify, or establish RACCs. Updating RACCs refers to amendments to the RACCs for products that are listed in the tables in § 101.12(b) and for which the NHANES 2003-2008 consumption data showed an increase or decrease in consumption of at least 25 percent. Modifying RACCs refers to changes to current RACCs in the tables in § 101.12(b) for which the NHANES 2003-2008 consumption data did not show an increase or

decrease in consumption of at least 25 percent for the preexisting product categories.

Establishing RACCs refers to the addition of products and the assignment of RACCs for such products that are not listed in preexisting tables in § 101.12(b).

In the proposed rule, we analyzed current food consumption data and determined that, for some product categories listed in the tables in § 101.12(b), the RACCs have changed. Additionally, we recognized that, since 1993, information regarding the RACCs for certain products not currently listed in the tables in § 101.12(b) has become necessary. These factors, combined with findings from the “Calories Count” report, information regarding the rise in obesity, increase in package sizes, and requests to establish and modify the RACCs, led us to propose amendments to the RACCs.

When determining when to update, modify, and establish RACCs, we analyzed consumption by combining data from the survey years of the NHANES, 2003-2004, 2005-2006, and 2007-2008 (NHANES 2003-2008 surveys), which provide an indication of the current amount of food being consumed by individuals at one eating occasion (Refs. 6, 7, and 8). Food consumption data from the NHANES surveys are released in 2-year cycles.

When determining whether to update an RACC, we first considered two factors. If both of these factors were not met, we did not consider updating the 1993 RACC. The first factor was to determine whether there was an adequate sample size from the NHANES 2003-2008 consumption data for each product in the 140 product categories. The data collection for NHANES, which is completed by Centers for Disease Control and Prevention (CDC), is used to assess intake by the U.S. population. Because CDC’s purpose in collecting NHANES data differed from our purpose in updating RACCs, sample sizes that CDC collected were not always adequate for considering updates to the RACCs. Thus, we retrospectively determined the

adequate, minimum required sample size based on the calculated design effect for each product within the product categories with a 90 percent confidence level and 20 percent margin of error. For some products, sample sizes are not large enough to obtain a reliable estimate of consumption. We have determined that for these products there is no compelling evidence (due to an insufficient number of samples) to consider updating the RACCs established in 1993.

The second factor was to determine if, for those products with a sufficient sample size, the median intake estimate from the NHANES 2003-2008 consumption data for the product significantly differed from the 1993 RACC for that product. We chose the value of 25 percent to represent a meaningful change based on our analysis of the data and after evaluating other values for percentage differences (e.g., 5 percent, 10 percent) when applied to the data. To be conservative, we determined if the 25 percent change in intake was significantly different from the 1993 RACC by comparing the upper or lower 95 percent confidence interval for the new median estimates to the either 0.75 or 1.25 times the 1993 RACC, respectively. If the new NHANES 2003-2008 consumption median estimate was higher than the 1993 RACC and the 95 percent lower confidence bound of the median estimate was greater than 1.25 times the 1993 RACC, we considered the new median to be significantly greater. If the new NHANES 2003-2008 consumption median estimate was lower than the 1993 RACC and if the 95 percent upper confidence bound of the median estimate was less than 0.75 times the 1993 RACC, we considered the new median to be significantly less (Ref. 12). When the consumption amount calculated from NHANES 2003-2008 surveys increased or decreased by at least 25 percent from the RACCs established in 1993 (i.e., less than 75 percent of the 1993 RACC or more than 125 percent of the 1993 RACC), we concluded that the current consumption amount needed to be updated; otherwise, we did not propose to update the 1993 RACC. In addition to determining

whether the consumption amount had increased or decreased at least 25 percent from the 1993 RACC, we considered the skewness of the data. If the intake distribution was skewed and we could not rely on the median intake estimate from the NHANES 2003-2008 consumption data to propose a change in the RACC, we examined the data from the Food and Nutrient Database for Dietary Studies (FNDDS) 4.1 (Ref. 25). The data from FNDDS provides the “reasonable consumption amount,” which we used to assist in our decision about whether to propose a change to the RACC. The reasonable consumption amount is a default consumption amount of food that researchers have defined and is used by NHANES when survey participants cannot recall the amount of food that was consumed at one eating occasion (Ref. 25). If the reasonable consumption amount for the product was consistent with the median intake estimate, we considered whether to propose a change to the 1993 RACC on a case-by-case basis. If the median intake estimate from the NHANES 2003-2008 consumption data was not consistent with the reasonable consumption amount for the product, and if a conversion to a common household measure is applicable for the product, we then looked to see if there was a significant difference between the median intake estimates from the NHANES 2003-2008 consumption data for the product, converted to an applicable common household measure, and the 1993 RACC for the product.

We received multiple comments asking for clarification or discussing our proposed amendments to specific RACCs or product categories. In the preamble of the proposed rule (79 FR 11989 at 12005), we invited comment on whether we should propose changes to other product categories, including products identified as products of concern in comments to the ANPRM. Several comments recommended that we change RACCs for some of these additional product

categories. We discuss these comments in section III.D.2. Comments relating to changing RACCs for specific product categories appear in alphabetical order, by product category.

1. Methodology Used to Determine When to Change RACCs

(Comment 35) Many comments supported the proposed changes to the RACCs and the methods used to update the RACCs. Many comments were in favor of the 25 percent criterion to determine if a change was statistically significant. One comment stated that the methodology used is consistent with the statutory mandate to base serving sizes on the amount customarily consumed and provides for a consistent approach across all food categories. Another comment stated that the comment analyzed newer NHANES consumption data (NHANES 2009-2010) for certain product categories and found that the results for the product categories analyzed were the same as our results when looking at NHANES 2003-2008 survey data.

Other comments questioned the methodology used to determine when to change the RACCs. Comments questioned why 25 percent was used as the criterion to determine when a change in RACCs was statistically significant. Some comments stated that the 25 percent cutoff is arbitrary and that proposing to update only RACCs with changes of 25 percent or greater neglects some categories that deserve reevaluation due to their impact on public health. Other comments questioned why we only looked at NHANES 2003-2008 data. The comments questioned why we did not consider newer consumption data in our analysis of when to make changes to the RACCs.

(Response 35) We chose the value of 25 percent to represent a meaningful change based on our analysis of the data and after evaluating other values for percentage differences (e.g., 5 percent, 10 percent), when applied to the data. To be conservative, we determined if the 25 percent change of intake was significantly different from the 1993 RACC by comparing the

upper or lower 95 percent confidence interval for the new median estimates to the either 0.75 or 1.25 times of the 1993 RACC, respectively. The 95 percent level of confidence is a general benchmark that is widely accepted in statistics and provides a conservative estimate to determine whether the recent nationwide consumption data capture the actual change of the amount being consumed from the 1993 RACC while taking into account for the variability of the measurement when collecting dietary intake data for the U.S. population. We have not modified our methodology in this final rule.

With regard to why we did not look at newer NHANES consumption data, the nationwide food consumption data are released every 2 years and with 2-year lag time (e.g., the NHANES 2007-2008 consumption data were released in 2010). The current RACCs, which were established in 1993, are based on data from Nationwide Food Consumption Surveys (1977-1978 and 1987-1988) conducted by USDA. The 2007-2008 NHANES data were the most recent consumption data available at the time that we conducted our analysis. We will continue to monitor consumption trends and update RACCs in the future as needed. Any consideration of newer consumption data would be addressed in a future rulemaking.

2. Changing RACCs for Specific Product Categories

(Comment 36) After-dinner confectionaries--We received one comment on the proposed RACC for after-dinner confectionaries. The comment supported the 10 g RACC for this product category, but requested that we provide clarification regarding the description of the product category. Specifically, the comment requested that any product marketed as an “after-dinner confectionery” or “after-dinner mint” and that is available in units of 10 g or less be included in the “after-dinner confectionaries” product category. The comment pointed out that all of these products have similar dietary usage. Examples given of products that should be included in the

after-dinner confectionaries product category were: (1) Small chocolate squares that are similar in size to after-dinner mints and intended to be used like mint wafers and (2) “butter mints” that are often displayed on restaurant counters for customers to take with them as they leave following a meal. The comment also recommended that we adopt the spelling of confectionaries as “confectioneries.”

(Response 36) We agree with this comment and agree that, generally, chocolate squares, butter mints, and similar products would be included in the “after-dinner confectionaries” product category since these products have similar dietary usage as after-dinner confectionaries. We also agree that confectioneries is the more widely used spelling and are amending table 2 in § 101.12(b) to reflect this spelling.

(Comment 37) Alfredo sauce--One comment opposed placing Alfredo sauce in the “Minor main entrée sauces (e.g., pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce” product category. The comment stated that the amount of sauce typically consumed for other sauces in this product category is much less than the typical amount of Alfredo sauce used to coat a serving of pasta. The comment said that several large Italian restaurant chains were contacted and those chains stated that they typically use as much Alfredo sauce as tomato sauce. The comment requested that we keep Alfredo sauce in the “Major main entrée sauces, e.g., spaghetti sauce” product category with an RACC of 125 g.

(Response 37) Consumption data for Alfredo sauce is consistent with other products in the minor main entrée sauces product category. While some may use Alfredo sauce in the same manner as tomato sauce, others use Alfredo sauce in the same manner as pesto sauce, which is also in the minor main entrée sauces product category. Because this product can be used in

either way, we must rely on consumption data, which shows that people are typically consuming less Alfredo sauce than spaghetti sauce. Therefore, we are finalizing our decision to place Alfredo sauce in the “Minor main entrée sauces (e.g., pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce” product category.

(Comment 38) All other candies--We received one comment that supported our proposal to amend the RACC of the “All other candies” product category to 30 g. We received no comments that opposed this amendment. The supporting comment noted that the 30 g RACC was consistent with industry analyses of national food consumption data and other data sources, which suggested that Americans typically consume candy in moderation. The comment also indicated that the confectionery industry has been supporting messages that endorse eating candy in moderation, and has been promoting this concept by marketing individually wrapped candy units in moderate portion sizes. Further, the comment expressed concerns that lowering the RACC to 30 g for the “All other candies” product category may affect the ability of manufacturers to make nutrient content claims for certain products. The comment requested that we consider updating the requirement that foods with smaller RACCs meet the nutrient criteria per 50 g for the purpose of making nutrient content claims and that we allow public comments on the implications to nutrient content claim requirements that are affected by the proposed rule.

(Response 38) We agree with the comment to the extent that it supports establishing a 30 g RACC for “All other candies” and are finalizing the change in RACC to 30 g. We decline, however, to reopen the comment period on the proposed rule or to amend the 50 g criteria for products that have RACCs of 30 g or less. We accepted comment on all issues pertaining to the impact that the RACCs have on nutrient content claims. We believe the comment period on the

proposed rule provided a sufficient opportunity to comment on this and other related issues. As discussed in section III. E., once this final rule and the Nutrition Facts final rule are published, we plan to assess the impacts of these rules on claim eligibility. We intend to consider issues such as whether any changes in eligibility for claims continues to help consumers construct healthful diets and whether the criteria for claims, including the 50 g criteria for products that have RACCs of 30 g or less, remain appropriate. However, as we noted in the proposed rule, changes in the eligibility to bear claims may be appropriate for some foods in light of changes in the amounts of food being customarily consumed (79 FR 11989 at 12016).

(Comment 39) Appetizers, hors d'oeuvres, mini mixed dishes, e.g., mini bagel pizzas, breaded mozzarella sticks, egg rolls, dumplings, potstickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins--Some comments supported the new Appetizers product category. The comments stated it is appropriate to establish a separate category for these smaller-sized versions of the current product category "Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches" in the "Mixed Dishes" general category because appetizers will be consumed in smaller amounts than the current mixed dishes product category based on their intended use. Some comments stated that this new product category would align with USDA labeling requirements for similar products.

One comment requested that, based on the similarities between the products that qualify for the "Mixed Dishes" general category and the new product category for Appetizers, we consider allowing products in the new product category for Appetizers to be eligible for a "lean" claim and requested that we clarify that products in the Appetizer category are eligible for a "lean" claim provided they meet the appropriate criteria. The regulations for "lean" claims

currently permit, in part, products that fall within the product category of “Mixed dishes not measurable with cup” to bear the claim, provided they contain less than 8 g total fat, 3.5 g or less saturated fat, and less than 80 mg cholesterol per RACC (§ 101.62(e)(2)).

(Response 39) We agree that establishing a separate product category for appetizer products is necessary. Consumption data shows that appetizers are consumed in smaller amounts than products in the mixed dish product category. The median consumption for mini pizza rolls is 83 g and for meatless egg rolls is 57 g. Appetizers are foods served before a meal, while products in the mixed dish product category are foods primarily used as entrées or main dishes (Ref. 26). We also note that the products in this new product category (e.g., mini pizza rolls) are similar to those found in a category in USDA’s Guide to Federal Food Labeling Requirements for Meat and Poultry Products (USDA’s Guide) (Ref. 27), which will allow consumers to compare nutrition information across food labels for these types of products. In terms of the “lean” claim, we note that while products in the Appetizers product category that were previously in the “Mixed dishes not measurable with cup” product category no longer fall under the requirements of § 101.62(e)(2), such products would be permitted to use a “lean” claim on their label if the products satisfy the requirements of § 101.62(e)(1).

(Comment 40) Fruits used primarily as ingredients, avocado--Some comments supported updating the RACC for avocado from 30 g to 50 g. The comments stated that updating the “Fruits used primarily as ingredients, avocado” product category will give Americans more reasons to choose avocados and increase their fruit and vegetable intake. The comment stated that the change in the avocado RACC will help Americans meet their nutrient needs, including some nutrients identified in the 2010 Dietary Guidelines for Americans as being of public health concern (e.g., fiber and potassium). The comments said that updating the RACC for fresh

avocados to 50 g (i.e., a $\frac{1}{3}$ medium avocado serving size) would contribute certain nutrients to the diet.

(Response 40) While this final rule affirms our decision to update the RACC for avocado, our decision to update the RACC was based on consumption data, rather than a desire to promote specific products or product categories.

(Comment 41) Bagel Thins, Mini Bagels--One comment requested that we include bagel thins and mini bagels in the bread product category, with an RACC of 50 g, instead of the new “Bagels, toaster pastries, muffins (excluding English muffins)” product category with an RACC of 110 g. The comment stated that bagel thins are a smaller, more calorie-conscious alternative to full-sized bagels and that each bagel thin, which is comprised of two slices, weighs 46 g. The comment further stated that bagel thins are marketed as a perforated unit, like an English muffin, and are typically suggested for use in making sandwiches, so that a consumer can enjoy the taste and texture of a bagel without the full thickness and accompanying calories of a regular bagel. The comment stated that with the new “Bagels, toaster pastries, muffins (excluding English muffins)” product category, the serving size for this product would be two separate bagel thins.

The comment also expressed concern with the RACC for mini bagels, which are sold in 40 g servings. The comment stated that under the current RACC for bagels, each serving size is one mini bagel, but the proposed RACC would increase the serving size to three mini bagels. The comment argued that this change could in turn encourage consumers to eat more mini bagels than is recommended under the current RACC and requested that we establish a separate category for these products that takes into account this discrepancy in serving size and different intended use. The comment questioned whether NHANES data used to determine the RACC for bagels included products such as mini bagels and mini muffins as a separate item from their full-

size counterparts. The comment requested that if there is separate data for mini bagels and mini muffins, we establish a separate RACC for these mini products and recommended that we consider adopting a similar approach for other innovative foods to avoid the unintended consequence of suggesting a serving size larger than what consumers are likely to consume in a single eating occasion.

(Response 41) We note that bagel thins have a similar dietary usage to sandwich bread--namely, to make sandwiches--rather than that of traditional bagels (i.e., as a breakfast item that is often eaten with cream cheese or other toppings) (Ref. 26). In addition, a review of recipes that used bagel thins as an ingredient reveals that most recipes using bagel thins are recipes for sandwiches that used bagel thins in a comparable manner to bread (Ref. 28). Section 101.12(a)(7) states that “[t]he reference amount is based on the major intended use of the food....” The reference amount reflects the major dietary usage of the food because the major usage determines the customarily consumed amount (Ref. 29). Therefore, we would include bagel thins in the “Breads (excluding sweet quick type), rolls” product category. The product category name will remain unchanged, but we intend to indicate that this type of product will be in the “Breads (excluding sweet quick type), rolls” product category with an RACC of 50 g in future guidance concerning serving sizes.

With regard to mini bagels, we disagree with the comment and are finalizing the placement of mini bagels in the “Bagels, toaster pastries, muffins (excluding English muffins)” product category with an RACC of 110 g. RACCs are not recommended amounts; rather, RACCs are based on the amount customarily consumed. The comment argues that increasing the RACC for mini bagels will encourage a consumer to eat more, but the rationale for increasing the RACC is that consumption data shows that consumers are already eating more

bagel products. In order to allow consumers to make easy product comparisons we group products with similar dietary usage together. The primary usage of mini bagels, like regular-sized bagels, is as a breakfast item. NHANES does not provide information about mini bagels and mini muffins that is separate from their larger-sized counterparts, and we have identified no other data indicating that consumption levels differ between mini bagels and regular-sized bagels. Further, mini bagels have similar product characteristics to their larger-sized counterparts (e.g., both are doughnut-shaped yeast rolls with a dense, chewy texture and shiny crust) (Ref. 25). Therefore, we decline to establish a separate RACC for mini bagels.

(Comment 42) Coffee Beans, Tea Leaves, and Certain Plain Unsweetened Coffee and Tea Products--Some comments noted that products such as plain unsweetened coffee and tea are exempt from the nutrition labeling requirements under § 101.9(j)(4) because they contain insignificant amounts of all nutrients required to be declared in the Nutrition Facts label. These comments noted that the increased RACC for these products combined with the proposed mandatory declaration of potassium in “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” may cause unsweetened coffee and tea to have low but detectable levels of potassium, which would cause them to lose their current exemption from nutrition labeling. The comments stated that nutrition labeling on these products could pose challenges for Nutrition Facts labels on small packages. Therefore, these comments requested that we reexamine § 101.9(j)(4) and make any necessary adjustments.

(Response 42) We recognize the discrepancy between the explicit exemption from nutrition labeling for certain coffee and tea products under § 101.9(j)(4), and the changes to the RACCs and nutrient declaration requirements that generally subject such products to nutrition labeling requirements. Although we asked for comment in the proposed rule about all issues

pertaining to the proposed RACCs, we did not ask for comments specifically about the continued applicability of the exemption from nutrition labeling provisions under § 101.9(j)(4) in light of the proposed changes to the RACCs and the proposed changes to the nutrient declaration requirements under the proposed rule entitled “Food Labeling: Revision of the Nutrition and Supplement Facts labels.” We intend to consider the future applicability of the exemption with respect to coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors in a separate rulemaking. Until such time as we have had the opportunity for any future rulemaking, we intend to consider the exercise of enforcement discretion with respect to the mandatory nutrition labeling on any products that would have been exempt under § 101.9(j)(4) prior to the effective date of this final rule.

We also understand that providing Nutrition Facts labels on packages with limited space may be challenging for manufacturers. We have special labeling provisions for packages with limited space in existing regulations (see § 101.9(j)(13)(i)).

(Comment 43) Canned Fish--One comment discussed the “Fish, shellfish, or game meat, canned” product category. The comment opposed the increase in the RACC of fish, shellfish, or game meat, canned from 55 g to 85 g. The comment stated that the most common use for canned seafood was as an ingredient in sandwiches, and that the RACC for the canned fish product category should remain at 55 g. The comment stated that canned fish is comparable with the product category “Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters” and four product categories for meat and poultry products regulated by USDA (i.e., luncheon meat, luncheon products, canned meats, and canned poultry) (Ref. 27). The comment stated that the common usage for canned fish in recipes reflects a 55 g RACC since canned

seafood is typically used as an ingredient to prepare sandwiches, salads and casseroles. The comment also questioned the validity of the “reasonable consumption amount” of 85 g. The comment stated that the “reasonable consumption amount” is a default value that may be used to indicate the quantity consumed during the dietary recall survey tool when the participant cannot recall the amount consumed and that a typical 5 oz can of tuna will provide the consumer with two, 2 oz (56 g) servings; thus, using 85 g as the default “reasonable consumption amount” will inflate the consumption amounts by over 50 percent. The comment stated that the other serving size descriptions for canned tuna and other canned seafoods (e.g., canned salmon) used for the USDA FNDDS need to be updated to reflect current can sizes. For the product “Tuna canned, non-specified as to oil or water pack,” two of the size options are a 13 oz can with a drained tuna amount of 321 g and a 6.5 oz can with a drained tuna amount of 160 g. The comment expressed concern that the use of larger-than-available can sizes and default serving size values will artificially inflate the amount of canned seafood that is recorded during diet recall surveys.

The comment further stated that the current RACC allows canned seafood, in particular canned tuna, to be offered in different-sized cans that reflect one or more servings per can. For example, a 3 oz can is a single serving, a 5 oz can has two servings, a 7 oz can has two and a half servings, and a 12 oz can has four and a half servings. The comment stated that with the proposed change to an 85 g RACC and the proposal to require products with less than 200 percent of the RACC to be labeled as a single serving, the 3 oz, 5 oz, and 7 oz can sizes will all be labeled as a single serving but each with different serving sizes.

The comment also stated that there is an inconsistency in the codified table of the proposed rule. The comment stated that the “Fish, shellfish, or game meat, canned” product category in the right-hand column lists examples of label statements and that two of the

examples correspond to a 55 g RACC rather than the proposed 85 g RACC. The comment noted that the table states, “2 oz. (56 g/___ cup) for products that are difficult to measure the g weight of cup measure (e.g., tuna); 2 oz. (56 g/___ pieces) for products that naturally vary in size (e.g., sardines).” The comment asserted that the examples provided in the table should reflect the finalized RACC.

(Response 43) In response to the comment that expressed concern that increasing the RACC will make the product category “Fish, shellfish, or game meat, canned” not easily comparable with the product category “Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters,” although products in both of these product categories can be used to make sandwiches, the consumption data for the product categories is different enough to warrant different RACCs.

To address the comment that questioned the validity of using the reasonable consumption amount, this comment misunderstands the basis for the proposed RACC. The change in RACC for this product category was based primarily on median consumption data and not the reasonable consumption amount. While we agree that the reasonable consumption amount is a default value that may be used to indicate the quantity consumed during the dietary recall survey tool when a participant cannot recall the amount consumed, this information is not considered relevant to our proposed RACC for “Fish, shellfish, or game meat, canned.” The decision to increase the RACC for canned fish products is primarily based on the median consumption NHANES 2003-2008 data of 84 g. Since the reasonable consumption amount did not provide the main basis for which we determined the RACC, we disagree that using 85 g as the default “reasonable consumption amount” will inflate the consumption amounts by over 50 percent. The

2003-2008 median consumption is 84 g for fish, shellfish or game meat, canned, which is also similar to the reasonable consumption amount from the currently available FNDDS of 85 g.

To address the comment asserting that the serving size descriptions for canned tuna and other canned seafood used for the USDA FNDDS need to be updated to reflect current can sizes, we note that such data is developed by USDA, and not FDA. To the extent that the comment is asking that we rely on more recent data, the data we used to establish the RACC for canned fish is consistent with our use of data in NHANES as discussed in comment 34.

The fact that the recent data has shown an increase in consumption outweighs the argument that the current 55 g RACC is the amount that is currently used in recipes for sandwiches, salads, and casseroles and that more can sizes will be labeled as a single serving with an increase in the RACC. The data suggest that consumers are consuming larger amounts of canned fish compared to the 1993 RACC of 55 g and that labeling some larger can sizes as a single serving will accurately reflect how consumers are eating the product. In addition, while we recognize the impact that package size has on consumption levels, package sizes are not taken into consideration when determining RACCs, as we cannot predict what package sizes will be in the marketplace. Rather, consumption amount is the primary factor in determining RACCs.

We have addressed the error in the label statement of the new 85 g RACC in the codified section of this rule. The label statement will be changed to “3 oz. (85 g/___ cup)” and “3 oz. (85 g/___ pieces).”

(Comment 44) Cereal--We received several comments concerning the RACC for breakfast cereal. Some comments supported the decision to maintain the existing RACC for cereal, yet other comments questioned the decision to keep the RACC for medium weight cereals

the same despite a significant increase in consumption when compared to the 1993 RACC. The comments stated that ready-to-eat cereals are a common breakfast food, particularly for children and adolescents, who typically consume more than the RACC. The comments stated that many cereals are high in added sugars, which are particularly concerning for children. Some comments stated that the Children's Food and Beverage Advertising Initiative (CFBAI) has established voluntary criteria for the nutritional quality of cereals marketed to children (Ref. 30). The current CFBAI standard limits the advertising of cereals to ones that contain no more than 10 g of total sugar per serving (Ref. 30). The comments noted that if we increased the RACC for medium-dense cereals, fewer sugary cereals would meet CFBAI's advertising criterion, fewer would be marketed to children, and companies would reduce the sugar content of popular cereals to enable them to be marketed to children.

Other comments questioned why the serving size on the labels of cereals varies so much. For example, a box of one type of cereal may have a serving size of 1 cup, while a box of another cereal may have a serving size of ½ cup. Package serving sizes on cereal labels appear to have greater variation than other product categories.

(Response 44) The 2003-2008 median intake estimates for breakfast cereals, weighing between 20 g and 43 g per cup (mediumweight cereals) is 39 g, which is significantly different from the 1993 RACC of 30 g. However, we did not propose to update the RACC for this product category in order to keep the household measure most closely associated with the reference amount consistent with the product category "Breakfast cereals, ready-to-eat weighing less than 20 g per cup, e.g., plain puffed cereal grains" (lightweight cereals) and the product category "Breakfast cereals, ready-to-eat weighing 43 g or more per cup; biscuit types" (heavy weight cereals), for which existing RACCs are 15 g and 55 g, respectively (Ref. 31). Although

the serving sizes for low, medium, and heavyweight cereals may appear to be varied, they are all based on comparable volumetric amounts. The differences in the density (e.g., grams per cup) of cereals make for the variation in their serving sizes. A consumer would have to eat more of a lightweight cereal to equal the weight of a cup of a heavyweight cereal. For example, the weight of 1 cup of a lightweight cereal, such as a puffed rice cereal, could be equivalent to the weight of a ½ cup of a heavyweight cereal such as an oat bran cereal. The current cereal RACCs correspond to 1 cup of cereal for the various cereal densities. The decision to maintain the current RACC for mediumweight cereals was to be able to maintain the same volumetric serving size of cereal for all three product categories. This way, although it may not appear as such on labels, a consumer is actually comparing similar amounts in terms of volume regardless of the type of cereal.

In light of the comments, and consistent with our evaluation of consumption data, we have decided to update the mediumweight cereal RACC to 40 g (Ref. 32). This amount corresponds to a 1.1 cup equivalent. Mediumweight cereal has the largest sample size of the three cereal product categories. We have determined that ensuring consistency in the RACC for all three breakfast cereal product categories to reflect the current consumption of mediumweight cereal, which has the largest sample size of the three product categories, is more in line with the changes that we made in other product categories. No change to the RACC is needed for low-density breakfast cereals weighing less than 20 g per cup, as the existing reference amount of 15 g continues to correspond to 1.1 cups. To ensure consistency with lightweight and mediumweight cereals, we are updating the RACC for the heavyweight breakfast cereals weighing 43 g or more per cup from 55 g (corresponding to 1 cup) to 60 g (corresponding to 1.1.

cups). By making these amendments, the RACCs for all cereals will now correspond to 1.1 cups.

(Comment 45) Cupcake Filling--One comment requested that we establish an RACC for cupcake filling. The comment explained that cupcake filling is frosting, pudding, fruit preserves or other items that are used to fill a cupcake. The comment asserted that cupcake filling is different from cake frosting because it is a product that is made for the purpose of being used inside the cupcake and not on top of a cupcake or cake. According to the commenter, cupcake fillings use less frosting or other filling ingredient than is used to ice a cake, and products from various product categories can be used as cupcake fillings including pie fillings, non-dairy whipped topping, and frosting.

(Response 45) We recognize a need for an RACC for this specific food product as well as for other types of cake or pastry fillings. Cake, pastry, and cupcake fillings include fillings for products such as donuts, cakes, and cupcakes. However, because the proposed rule was silent about an RACC for cupcake filling, and because we intend to provide the opportunity for public comment on this specific issue, we intend to establish an RACC for this product category in future rulemaking and intend to add a suggested RACC of 1 tbsp for this product category distinct from the “Cake frostings or icings” product category in a future guidance document.

(Comment 46) Drink Mixes--Some comments discussed the two new drink mix product categories: “Milk, milk substitute, and fruit based drink mixes (without alcohol) e.g., drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)” and “Drink mixes (without alcohol): all other types (e.g., flavored syrups and powdered drink mixes).” The comments were generally in favor of the proposed changes to the drink mix product categories, but requested a revision to the fruit-based drink mixes. The comments requested that the

subcategory of “fruit-based drink mixes,” which includes fruit-flavored powdered drink mixes, be removed from the “Milk, milk substitutes, and fruit based drink mixers (without alcohol), e.g., drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)” product category with an RACC of “Amount to make 240 mL drink (without ice)” and added to the “Drink mixes (without alcohol): all other types (e.g., flavored syrups and powdered drink mixes)” product category with an RACC of “Amount to make 360 mL drink (without ice)” based on its primary use as a mix added to water. The comments stated that the categorization of drink mixes causes inconsistencies. For example, powdered tea mixes are currently in the amount to make 360 mL product category, and non-flavored tea mixes would have an RACC of 360 mL; however, fruit-flavored tea mixes (e.g., raspberry-flavored tea) would have an RACC of 240 mL. The comments stated that this categorization of drink mixes could foster confusion for consumers and lead to unnecessary and unwarranted changes for industry.

One comment asked for clarity on the categorization of liquid concentrate beverage mixes and requested that a subcategory for “liquid beverage concentrates” be added to the product category “Drink mixes (without alcohol): all other types (e.g., flavored syrups and product drink mixes),” with an RACC of 360 mL (12 fl oz), since this product subcategory is primarily added to water when consumed.

(Response 46) The proposed “Milk, milk substitutes, and fruit based drink mixers (without alcohol), e.g., drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)” product category is intended to contain drink mixes containing 100 percent fruit-based ingredients, such as fruit juice concentrate, which have similar dietary usages as 100 percent fruit juices or fruit drinks. This product category was not intended to include products that are fruit flavored. Therefore, a fruit-based drink mix with an RACC of 8 fl oz is necessary. However, we

understand the issue addressed in the comment and see that it is necessary to create an additional RACC for fruit-flavored drink mixes that have an RACC of 360 mL (12 fl oz). Therefore, we are revising the product category names to reflect the changes. We are clarifying that the 240 mL (8 fl oz) RACC product category is intended for fruit drink mixes that substitute 100 percent juice blends such as frozen fruit juice concentrates and that the 360 mL (12 fl oz) RACC product category is intended for powdered fruit-flavored drink mixes that are comparable to iced tea mixes and other beverages that have an RACC of 360 mL (12 fl oz). Fruit juice concentrates should have an RACC of 240 mL (8 fl oz), consistent with 100 percent fruit juices and fruit drinks. The name for the “Milk, milk substitutes, and fruit based drink mixers (without alcohol), e.g., drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)” product category is amended in § 101.12(b) to “Milk, milk substitute, and fruit juice concentrates (without alcohol) (e.g., drink mixers, frozen fruit juice concentrate, sweetened cocoa powder).” The category name for “Drink mixes (without alcohol): all other types (e.g., flavored syrups and powdered drink mixes)” will remain the same.

With respect to the comment concerning liquid beverage concentrates, the comment does not describe what a liquid beverage concentrate is. We are unsure if the products referred to are different than the fruit juice concentrates discussed previously. However, if the product is fruit flavored, rather than a fruit juice concentrate, then it should be included in the “Drink mixes (without alcohol): all other types (e.g., flavored syrups and powdered drink mixes)” product category with an RACC of 360 mL (12 fl oz).

(Comment 47) Fruit juice--Several comments supported keeping the RACC for fruit juice at 240 mL (8 fl oz). One comment stated that a 240 mL (8 fl oz) RACC is consistent with guidelines established by the American Academy of Pediatrics and the Robert Wood Johnson

Foundation (which both recommend 8 oz of juice for adults and older children), in addition to the 2010 Dietary Guidelines for Americans. The comment requested that all juice beverages have the same 240 mL (8 fl oz) RACC regardless of whether it is manufactured with still water or carbonated water.

(Response 47) Based on our review of the data as described in the proposed rule (79 FR 11989 at 12010), we agree that the RACC for fruit juice should remain at 240 mL (8 fl oz). Products that contain less than 100 percent and more than 0 percent fruit or vegetable juice and that meet the requirements under § 102.33(a) to be labeled as a juice “beverage,” “drink,” or “cocktail” have an RACC of 240 mL (8 fl oz) regardless of whether they are manufactured with still water or carbonated water. We note, however, that drink mixers do not fall within the product category “Juices, nectars, fruit drinks”; rather, products such as strawberry daiquiri mix and Bloody Mary mix are part of the product category “Drink mixes (without alcohol): all types (e.g., flavored syrups and powdered drink mixes).”

(Comment 48) Hazelnut spread--We received a comment requesting that we either: (1) Expand the existing product category for “Honey, jams, jellies, fruit butter, molasses” to include nut cocoa based spreads, such as hazelnut spread or (2) establish a new RACC of 1 tbsp for nut cocoa based spreads. The comment stated that hazelnut spread is currently in the product category “other dessert toppings” because it was considered to be comparable with chocolate syrup at the time of the 1991 proposed rule. The comment indicated that hazelnut spread is currently primarily used on bread or as a spread for snacks, crackers, and fruits. The comment also stated that the mean, median, and mode consumption amounts for hazelnut spread in NHANES are all equal to 1 tbsp.

(Response 48) We recognize a need for an RACC for hazelnut spread outside of the dessert product category. We agree that the primary usage of hazelnut spread is as a spread for bread instead of as a dessert topping. However, because the proposed rule was silent about an RACC for hazelnut spread, and because we intend to provide the opportunity for public comment on this specific issue, we intend to consider whether to move hazelnut spread to a different appropriate product category in a future rulemaking.

(Comment 49) Several comments questioned the regrouping of the “Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones)” product category and the “Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)” product category to the following product categories: “Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk” and “Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types novelties (e.g., bars, sandwiches, cones, cups).” The comments stated that the decision to increase the RACC for ice cream was arbitrary and that it is only by proposing to separate the ice cream product category into separate RACCs for bulk ice cream and novelties that we were able to determine that consumption of one of those categories (i.e., “bulk ice cream”) had increased by more than 25 percent compared to the 1993 RACC.

The comments stated that the separation of the ice cream category into two sub-categories raises an issue of consistency between the two product categories. The comments stated that the exact type of ice cream sold in a ½ cup individual novelty serving can be packaged in a larger bulk container such as a pint or ½ gallon. The comments stated that although the products will have identical formulations, the differing RACCs between the bulk and novelties package sizes would result in different criteria for the nutrient content claims such

as “low fat,” “fat free,” or “non-fat.” This would mean the same ice cream could meet the criteria for “low fat” when packaged in a small, novelty-sized cup, but not when it is packaged in a larger container. Similarly, a frozen yogurt or ice cream product may be considered a “good source” of calcium when dispensed from a bulk container, but not a good source of calcium when provided in a single-serve cup. One comment asserted that using two different RACCs depending upon the package size (e.g., bulk or single-serve cup) would create consumer confusion through the distinction in nutrient content claims each product would be permitted to make.

One comment requested that we remove the term ice milk from the product category name “Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk.” The comment noted that the standard for ice milk was abolished in 1994 when we acted on a citizen petition from the International Ice Cream Association and issued a final rule entitled “Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream” (59 FR 47072, September 14, 1994).

One comment stated that soft-serve products are distinct from traditional (hard pack) ice cream and frozen desserts. The comment asserted, for example, that a typical soft-serve ice cream has less fat, more milk solids, a lower sugar content, and a lower percent overrun (referring to the amount of air that is whipped into the product), and is generally eaten at a warmer serving temperature compared to a typical hard ice cream. The comment stated that a typical hard ice cream has a density of 1.0 weight ozs per 1.8 fl oz (128 g per cup), while a survey of the soft-serve ice cream industry revealed an average product density of 1.0 weight ozs per 1.25 fl oz (181 g per cup). The comment requested a new product category for soft-serve ice

cream named “Soft serve ice cream, soft serve frozen custard, soft serve gelato: All types bulk” with an RACC of ½ cup. The comment noted that there is precedent for delineation of products by differences in density--for example, “Cakes” are separated into categories of heavyweight, mediumweight, and lightweight; and “Breakfast cereals” are separated into categories by density (puffed, medium density, and biscuit type). The comment stated that because of their differences in density, such a separation seems appropriate for frozen dairy desserts as well.

(Response 49) With respect to the comments regarding the reorganization of the two product categories--“Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk” and “Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types novelties (e.g., bars, sandwiches, cones, cups)”--we have reconsidered our position on whether distinct product categories are necessary. Upon further consideration, we agree that bulk frozen dairy products are similar to novelty frozen dairy products, and that bulk frozen fruit flavored products are similar to novelty frozen fruit flavored products, both in terms of dietary usage and in terms of product characteristics. We recognize that the same type of ice cream sold in a ½ cup individual novelty serving can be packaged in a larger bulk container such as a pint or ½ gallon and that these products may have identical formulations. In order to allow for comparable frozen dessert products to be grouped together we are modifying the preexisting RACCs to create one combined product category with the product category name “Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups).” This change should also eliminate concerns expressed by comments that using two different RACCs depending upon the package from which the product is dispensed (e.g., bulk or single-serve cup) might be confusing to consumers.

In order to determine the median consumption amount for the product category “Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups),” we analyzed the NHANES 2003-2008 intake data for all products in this product category and found that the median consumption of these products is 0.7 cup. Under § 101.9(b)(5)(i), when the use of cups is the appropriate household unit in which to express serving size, the quantity in cups shall be expressed in $\frac{1}{4}$ - or $\frac{1}{2}$ -cup increments. Under this provision, 0.7 cups rounds to $\frac{2}{3}$ of a cup. Therefore, we are creating an RACC for the new product category “Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups)” of $\frac{2}{3}$ of a cup. The regrouping of these product categories allows for like products to have the same RACCs based on similar dietary usage, product characteristics, and customary consumption amounts.

With respect to the comment that requested that we remove the term “ice milk” from the product category “Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk,” we agree. Ice milk has not been included in the new frozen desserts product category.

With respect to the comment requesting a separate product category for soft serve ice cream, we decline to make this change. Bulk soft-serve ice cream has similar dietary usage and is consumed in the same manner as non-soft-serve ice cream (Ref. 26). Providing the same RACC for these two types of products allows consumers to easily compare nutrition information between the two products.

(Comment 50) Ice cream--Several comments addressed the change in the RACC for ice cream from $\frac{1}{2}$ cup to 1 cup. Some comments favored the proposed changes to the RACC for ice

cream, while others were opposed to it. The comments in favor of the 1 cup RACC for ice cream stated that the new RACC was more reasonable and consistent with the amount that a person typically consumes.

Other comments stated that a ½ cup measure for ice cream is a more practical and realistic reference amount. One comment stated that a ½ cup of ice cream is not misleading. The comment noted that the common household ice cream scoop dispenses 8 servings of ice cream per quart, or exactly a ½ cup of ice cream. The comment further noted that the ½ cup measure is a simple common reference point that consumers clearly understand and that, with ongoing concerns about obesity in America, it is important to have simple tools to help consumers manage their weight. A few comments suggested that if we increased the RACC to 1 cup, consumers might interpret the RACC as an indication that two scoops of ice cream is an appropriate portion.

(Response 50) With respect to the comments stating that the RACC for bulk ice cream should remain at ½ cup because this is the typical amount in a household scoop, the comment did not provide data to confirm that a ½ cup ice cream scoop is the most common household size. There are ice cream scoops that are commercially available to consumers in sizes ranging from 0.5 oz (1 tablespoon (tbsp)) to 5 oz (1 cup) (Ref. 33). Although it may be common for ice cream scoops to scoop ice cream in the amount of ½ cup, ice cream scoop sizes vary. We also note that the comment provided no support for the assertion that consumers eat one scoop of ice cream. It is less subjective and consistent with FDA's legal authority to base the RACC on the amount customarily consumed. As explained in comment 49, we are finalizing an RACC for the product category "Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juice: all types bulk and novelties (e.g. bars, sandwiches, cones, cups)" of ⅔ of a cup.

With respect to the comment that stated that increasing the RACC for ice cream would be confusing to consumers and encourage them to eat more, we note that some consumer comments on the ANPRM and the proposed rule suggested strongly that the existing RACC is misleading and requested that the RACC for ice cream be based on a more realistic amount. To help ensure that consumers understand the meaning of changes to the serving size portion of the Nutrition Facts label, we intend to conduct nutrition education to help clarify the meaning of the serving size and RACCs after this rule becomes effective.

(Comment 51) Some comments questioned the density measurements we used when converting from the amount of ice cream consumed, as reported in NHANES data, to the common household measure based on cups in order to determine the RACC for bulk ice cream. One comment stated that a memo to the file for the proposed rule (Ref. 31) states the household units were calculated using the following conversion factors: 1 oz of ice cream or frozen yogurt = 1.5 fl oz; 1 cup = 8 fl oz (citing § 101.9(b)(5)(viii)). The comment agreed with this conversion factor based on the air typically incorporated into ice cream, but did not believe we applied the conversion factor correctly. The comment stated that the median weight for “Ice cream, bulk, and regular” from 2003-2008 NHANES is 116 g, but that, in the proposed rule (79 FR 11989 at 12012), we stated that the “[c]urrent consumption data for bulk ice cream has increased to 0.875 cup, which is closer to 1 cup as compared to the current RACC of ½ cup.” The comment stated that, if the footnote conversion factor were applied to the median serving size of ice cream expressed by weight, it would result in a lower value of 6.108 fl ozs or 0.767 cup, which would round in household measures to ¾ of a cup ($116 \text{ g} / 28.35 \text{ g per oz} = 4.09 \text{ oz} \times 1.5 = 6.138 \text{ fl oz}$) and that this corresponds to a density value of 151 g per cup for ice cream and frozen yogurt (i.e., $(1 \text{ oz} / 1.5 \text{ fl oz})(8 \text{ fl oz} / 1 \text{ cup})(28.35 \text{ g} / \text{oz}) = 151 \text{ g} / \text{cup}$). The comment noted that a ¾ cup

household measure for bulk ice cream reflects current consumption data and product composition and said that the comment relied upon used the most current density measurement for ice cream of 148 g per cup, based on NHANES data from 2003-2010, which will result in an RACC of $\frac{3}{4}$ cup for bulk ice cream. The comment stated that when the 148 g per cup density measurement for ice cream is applied to the 2003-2008 NHANES median amount consumption per eating occasion (116 g), the household measure is calculated at 0.783 cup (6.26 fl oz or $\frac{3}{4}$ cup). The comment stated that consumers now favor more dense ice creams, and that the ice cream industry has changed processing and formulations to meet consumer expectations. The comment stated that if the 163.5 g density was applied to the 120 g serving size (2003-2010 NHANES) the household measure would also round to $\frac{3}{4}$ cup (120 g median serving NHANES 2003-2010/163.5 g per cup = 0.736 cup (5.89 fl oz or $\frac{3}{4}$ cup).

(Response 51) With respect to the comments questioning the density measurements used to calculate the RACCs, the comment used a different procedure to calculate the density measurements than we did in the proposed rule. When we calculate density, the median ice cream consumption in cups is based on the median consumption distribution of all varieties of ice cream using the consumption amount for each individual product (e.g., strawberry ice cream, chocolate ice cream). The consumption amount is then converted from gram weight to volume in cups for each individual product. The method described in the comment, in contrast, looked at the density of the product category as a whole--instead of the consumption amount for each individual product--and converted the median of gram weight amount to the median consumption in cups to determine the median of consumption amount in a household measurement. Therefore, 0.875 cup was the median consumption amount for the bulk ice cream product category discussed in the proposed rule based on consumption distribution when each

participant's ice cream consumption has already been converted from gram weight to volume in cups, and there is no further conversion for that median gram weight estimate. We did not consider a $\frac{3}{4}$ cup RACC for bulk ice cream to be appropriate because the consumption data shows that 0.875 cup (half way between 0.75 cup and 1 cup, therefore, rounding up to 1 cup) is the amount customarily consumed, not 0.736 cup as stated in the comment. As discussed previously in response to comment 34, our calculations relied on 2003-2008 NHANES data rather than 2003-2010 data. As explained in comment 49, we have combined the proposed categories "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk" and "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types novelties (e.g., bars, sandwiches, cones, cups)" into one product category, "Ice cream, frozen, yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juice: all types bulk and novelties (e.g., bars, sandwiches, cones, cups)." The RACC for the new product category is $\frac{2}{3}$ of a cup. The methodology used in determining this reference amount is consistent with the methodology we used in the proposed rule (Ref. 32).

(Comment 52) Foods for Infants and Children 1 through 3 Years of Age--We received one comment that supported changing the RACC for the "Dinners, dessert, fruits, vegetables or soups, ready-to-serve, strained type" product category from 60 g to 110 g. The comment noted that the proposed RACC was similar to the consumption amount calculated by the comment after evaluating available data. The comment also requested changes to the product categories for infant and toddler (children 1 through 3 years of age) foods. The comment stated that the number of foods available and specifically marketed to infants and children 1 through 3 years of age has grown significantly since the 1993 RACCs were created, including yogurt, pasta, snacks,

breakfast cereal, entrées, and main dish items. The comment stated that many foods now available for infants and young children 1 through 3 years of age do not have specific RACCs, and that more guidance on RACCs for foods for infants and children 1 through 3 years of age should be codified to ensure consistency in serving sizes, labeling and claims for foods marketed for infants and young children. The comment included a table of recommendations for new product categories for foods for infants and children 1 through 3 years of age, along with proposed corresponding RACCs.

(Response 52) We agree more products for infants and children 1 through 3 years of age are currently on the market than were available in 1993. At the time of publication of the serving size proposed rule, there was limited data for these new types of infants and toddler foods in NHANES. We intend to review the data submitted in the comment and address these additional foods in a separate rulemaking.

(Comment 53) Milk and soy beverages--One comment supported our proposal to modify the product category “Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa” to “Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage.” The comment stated that it agreed with the change in name and is gratified to see our acknowledgement and proper use of the term “soy beverage.”

(Response 53) The final rule uses the new product category name of “Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage.” We note, however, that our adoption of this product category name does not constitute an official “acknowledgement” that the term “soy beverage” is the sole appropriate descriptor for all beverages containing soy.

(Comment 54) Mixed dishes measurable with cup--We received a comment asking us to change the label statement for mixed dishes measurable with cup in § 101.12(b), table 2 from 1 cup (_ g) to “_ cup (_ g).” The comment stated that the current label statement of 1 cup (_ g) is not applicable for fully cooked frozen fried rice that only requires heating to be ready-to-serve. The comment stated that it was requesting a change to the label statement because not all “almost-ready-to-serve products” maintain the same density after heating. The comment stated that in order to obtain 1 cup of ready-to-serve cooked rice, it is necessary to measure 1 1/3 cups of the frozen rice and that the correct serving size should be 1 1/3 cups. The comment requested that the label statement for mixed dishes measurable with a cup be left blank and written as “_ cup (_ g).”

(Response 54) We disagree with changing the label statement for this product category based on the information provided in the comment. Section 101.12(b), table 2, footnote 2 says that the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (e.g., heat and serve, brown and serve), and if not listed separately, the reference amount for the unprepared form (e.g., dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. This means that although the RACC for mixed-dish products is 1 cup, this amount is for the prepared product. The serving size, however, must represent the product as packaged. Because the weight of the cooked rice depends on the amount of water used in the preparation, the amount required to make one reference amount in cooked form can vary widely. Additionally, as we explained in the 1993 serving size final rule, establishing a reference amount on a cooked basis could allow manipulation of the reference amount for dry rice (58 FR 2229 at 2253). The serving size,

therefore, is the amount of the frozen rice, expressed in a household measure, which will make 1 cup when prepared according to package directions.

We also disagree with the assertion in this comment that fully cooked frozen fried rice is an almost ready-to-serve product. Frozen rice is not an almost ready-to-serve product; rather, it is an unprepared product because it is frozen and requires cooking before being consumed. This means that the product should be labeled with the reference amount of 1 cup of rice, using the amount of frozen rice required to make 1 cup of prepared rice to determine the nutrition values on the label.

(Comment 55) One comment supported maintaining the product category “Not measurable with cup e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches,” under the general category “Mixed Dish” at the current RACC of 140 g, add 55 g for products with gravy or sauce topping. The comment stated that it analyzed consumption data from NHANES 2003-2010 and found that the median estimated intake for pizza (all crust types) is 169 g, or 21 percent of the current RACC, which is below the amount to be considered significant and does not indicate that the RACC needs to be updated. The comment stated that this supports our assessment that maintaining the current RACC is still an appropriate representation of amounts customarily consumed for this product category.

(Response 55) We agree that no change to the RACC for the “Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches” product category is necessary. We note, however, that our analysis is based on 2003-2008 NHANES consumption data, rather than 2003-2010 consumption data as this comment purported to use.

(Comment 56) Muffins--One comment opposed increasing the RACC for muffins from 55 g to 110 g. The comment questioned whether we included muffins sold in restaurants in the

data analysis used to update the muffin RACC. The comment stated that the sizes of packaged muffins sold in the retail store were closer to or less than the current 55 g RACC for muffins. In contrast, the sizes for muffins sold in cafes and restaurants are substantially larger and closer to the proposed RACC of 110 g. The comment stated that 110 g does not reflect the amount of packaged retail muffins customarily consumed in one eating occasion, particularly given that muffins are consumed in discrete units.

The comment also asked for clarification on whether products such as mini-muffins packaged in a multipack of pouches that typically contain about 5 mini muffins per pouch, with a weight of about 47 g per pouch, will be required to declare the serving size on the outer carton of the multipacks of pouches as 2 packs (94 g) instead of 1 pack (47 g). With the increase in the RACC for muffins to 110 g, 2 packs of mini muffins would be the amount that most closely approximates the RACC. The comment suggested that one pouch would be a more appropriate serving size.

(Response 56) The 2003-2008 NHANES consumption data captures all possible sources of the food (e.g., restaurant, vending machine, grocery store). Our analysis considered all sources of food because the data available does not allow us to distinguish consumption at home from consumption in retail stores, restaurants or other eating establishments. We note, however, that only one-third of the food represented in NHANES data is consumed away from home, meaning that the majority of consumption reported is food eaten in the home. Food eaten at home is more likely to be packaged food. The 2003-2008 NHANES data shows an increased consumption for muffins, so we are updating the RACC accordingly. We also note that muffins that are sold in restaurants may be distributed through retail stores.

With regard to the request for clarification on how to label a multipack of pouches of mini muffins, this would depend on a number of factors, including whether the pouches bear Nutrition Fact panels. As discussed in the response to comment 10, manufacturers of packages that weigh less than 200 percent of the RACC each that are contained within a larger container have the option of labeling each individual package with a Nutrition Facts panel, and then labeling the outer container to state the number of servings as the number of individual packages within the outer container in accordance with § 101.9(b)(8)(iv). As is discussed in the response to comment 9, a product that is packaged and sold individually, i.e., a container that bears a Nutrition Facts panel, is considered a single-serving container if it contains less than 200 percent of the RACC, and would be required to provide dual-column labeling if it contains at least 200 percent to 300 percent of the RACC, unless an exception from the requirement applies.

(Comment 57) Pasta with sauce--Several comments requested that we increase the RACC for pasta with sauce. The comments stated that consumption for pasta with sauce increased by 50 percent to 1.5 cups. One comment noted that we did not propose to increase the RACC for pasta with sauce because the two products with the largest samples sizes in the product category--“Rice, flavored” (consumed by 3,477 respondents) and “Mixtures with sauce” (consumed by 2,919 respondents)--did not increase to more than 1 cup and that pasta with sauce was the third most popular food group (consumed by 2,871 respondents). The comment disagreed with our rationale to keep the entire “measureable by a cup” category at 1 cup because it stated that the foods in that product category vary so widely (e.g., pot pies, lasagna and ravioli, casseroles, chili and stew, mixtures with sauce, and mixtures without sauce). The comment requested that we increase the RACC for pasta with sauce to 1.5 cups based on the 2003-2008 NHANES consumption data. The comment stated that lumping pasta with sauce in with other foods in the

“Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.” product category under the “Mixed Dishes” general category violates the FD&C Act, which requires RACCs to be based on amounts “customarily consumed.”

(Response 57) While consumption of pasta with sauce did increase since we established the 1993 RACCs, as the comment noted, consumption for other products in the product category with larger sample sizes did not increase. All of the products in this product category are mixed dishes that are generally used as entrées. Products in this category are mixtures and usually contain starch (e.g., rice, pasta), dried beans and/or animal source ingredients (e.g., cheese, fish, shellfish). They come with or without vegetables (Ref. 34). Thus, all of these products are comparable in that they have similar dietary usage and product characteristics (e.g., they are mixed dishes that are measurable with a cup). Frozen entrées are included in the mixed dishes product category. One manufacturer may have a product line with a variety of frozen meals that includes frozen spaghetti with tomato sauce, frozen lasagna, frozen rice mixture, and frozen macaroni and cheese. We note that it would not be helpful to a consumer who is choosing among the different varieties of the same product line if one box shows a serving size that is based on the RACC of 1 cup, while another box which has similar packaging, and is part of the same product line, shows an RACC of 1.5 cups. It is important that the RACCs of comparable products be similar to help consumers to more easily compare nutrition information on the Nutrition Facts label across similar products.

With respect to the comment asserting that including pasta with sauce in the product category “Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.” under the “Mixed Dishes” general category violates the FD&C Act, we disagree. Products in this category are mixtures that usually contain starch (e.g., rice, pasta),

dried beans and/or animal source ingredients (e.g., cheese, fish, and shellfish) (Ref. 34). These products have similar dietary usage and are usually consumed in the same way as an entrée or main dish. Other comparable products in this product category include casserole, lasagna, and macaroni and cheese. The RACC for pasta is based on the amount that is customarily consumed for products in this product category. We disagree with the assertion that grouping foods in such a manner violates the FD&C Act. We followed the methodology used for all products categories when determining the RACC for the “Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc.” product category under the “Mixed Dishes” general category. Products with a larger sample size in the product category did not show a significant amount of change; therefore, we did not update the RACC for pasta with sauce.

(Comment 58) We received a comment requesting us to clarify if plant-based beverages with added ingredients are included in the proposed product category for “Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage.” The comment stated that the proposed rule does not discuss the appropriate RACC for plant-based beverages with added ingredients, such as protein, fiber, or fruit, including those that may be positioned as a plant-based “smoothie.” The comment argued that plant-based beverages with added ingredients should be included within the RACC for milk and milk-substitute beverages because plant-based beverages with added ingredients are more nutrient dense than a carbonated or non-carbonated beverage like a soda or water, and typically contain higher levels of protein, vitamins, and minerals.

(Response 58) We did not intend plant-based beverages with added ingredients to be included in the proposed product category for “Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage,” and we disagree that

plant-based beverages with added ingredients should be included in this product category.

Whether or not plant-based beverages with added ingredients are more nutrient dense than a carbonated or non-carbonated beverage like a soda or water depends on the contents of a specific product; however, we do agree that plant-based beverages do not belong in the same product category as carbonated and non-carbonated beverages. A plant-based beverage such as a smoothie is a beverage that is made by blending fruit with yogurt, milk, or ice cream until it is thick and smooth (Ref. 26). Plant-based beverages with added ingredients are otherwise more similar to other items in the product category “Shakes and shake substitute, e.g., dairy shake mixes, fruit frost mixes” than to products in the category “Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage.” The comment’s description of a plant-based mix includes products with fruit or cocoa as added ingredients. Fruit and cocoa are commonly added ingredients in milkshakes (Ref. 26). Regardless of the distinction between product categories, we note that the RACC for the milk and milk substitute product category is the same as the RACC for the milkshake product category.

(Comment 59) Powdered candies and liquid candies--We received one comment in support of our proposals to add “powdered candies” and “liquid candies” to the product category currently designated as “Hard candies, others” and to establish an RACC of 15 mL for liquid candies and 15 g for powdered candies and all other hard candies. The comment noted that the proposed RACCs are consistent with “suggested RACCs” provided in FDA guidance and are consistent with current industry practices. The comment also supported our proposal to rename this product category “Hard candies, others; powdered candies, liquid candies” to indicate that powdered and liquid candies would now be included in this product category.

(Response 59) We agree with this comment. Powdered candies may be dispensed from straws, and liquid candy can be dispensed from small bottles or waxy containers. This final rule establishes an RACC of 15 g for powdered candies and an RACC of 15 mL for liquid candies and includes both in the product category “Hard candies, others; powdered candies, liquid candies.” Additionally, the label statement for this category in table 2 of § 101.12(b) will include label statements for powdered candies (“____ straw(s) (____ g) for powdered candies”) and liquid candies (“____ wax bottle(s) (____ mL) for liquid candies”).

(Comment 60) Powdered coffee creamer--Some comments requested that we increase the RACC for powdered coffee creamer from the current RACC of 2 g, which is equal to 1 teaspoon (tsp). The comments stated that the NHANES data show that the median consumption of powdered coffee creamer has doubled to 4 g, or 2 tsps. One comment stated that consumers use much more than 2 g or 4 g and suggested that we use 6 g, or 1 tbsp, as the RACC. The comment stated that we should increase the RACC for powdered creamers to 1 tbsp so that it can be the same serving size as is used for liquid creamers.

(Response) The current 1993 RACC for “Cream or cream substitutes, powder” is 2 g (or 1 tsp). Although the median 2003-2008 NHANES consumption is 4 g, the data available in 2003-2008 NHANES were insufficient to provide adequate information on which to base a change from the 1993 RACC (Ref. 31). The data available did not meet the criteria to update the RACC from the 1993 RACC of 2 g because there was not an adequate sample size to provide a reliable median intake estimate. Therefore, we did not propose to change the RACC for powdered creamers.

With respect to the comment that suggested we use the same RACC for both liquid and powdered creamers, we disagree. Powdered creamer and liquid creamer have different product

characteristics (e.g., powder vs. liquid), and the household measurement for the two types of products is different. A weight measurement is used for powdered creamer, and a volume measurement is used for liquid creamer. Additionally, the consumption amounts for powdered and liquid creamers are not similar. The current RACC for “Cream or cream substitute, liquid” did not show a significant increase from the current RACC of 15 mL (or 1 tbsp); therefore, we did not propose to change it.

(Comment 61) Soup--Several comments addressed the “All varieties” product category under the “Soups” general category. Most comments requested that we update the RACC for canned soup. The comments stated that the current RACC for soups is too small and that many consumers can eat an entire can of soup in one sitting. Some comments referred to a single serving container of soup that is typically 15 oz and lists the serving size as 2 servings.

(Response 61) While we understand the concern that some canned soups that appear to be single-serving containers are being labeled as having more than one serving, consumption data for this product category has not significantly increased. However, we note that under the new requirements for single-serving containers finalized in this rulemaking, products that are packaged and sold individually and that contain less than 200 percent of the RACC will be labeled as single-serving containers. Additionally, under the new dual-column labeling requirements finalized in this rulemaking, products containing at least 200 percent but less than 300 percent of the RACC will be required to provide nutrition information for the full container. Pursuant to this rule, canned soups that are currently labeled as containing “about 2 servings” will be required to provide nutrition information for the entire container, either using a single-serving container label or using a voluntary or mandatory dual-column label format.

(Comment 62) Sugar--One comment opposed updating the RACC for sugar. The comment stated that a change in consumption data is not enough to justify a change in the RACC. The comment noted that consumption data used in the 1991 proposed rule also showed that sugar should have an RACC of 8 g, but we nonetheless chose to finalize the RACC at 4 g in 1993. The comment stated that consumption data for sugar is limited and that we should, therefore, take into account other sources of information when determining the RACC. The comment stated that consumers typically add sugar to foods 1 tsp at a time and that the proposed 8 g RACC (2 tsp serving size) is cumbersome for most consumers who do not measure out sugar 2 tsp at a time. The comment also stated that if we update the RACC for sugar, consumers will believe that 2 tsp is the recommended serving size.

(Response 62) The decision to update the RACC for sugar is based on consumption data. The methodology used in the decisionmaking process for updating the RACC for sugar is the same methodology used to determine when to update the RACC for all product categories. While the current RACC for sugar has been used for more than two decades, RACCs are based primarily on the amount that is customarily consumed. Consumption data shows that the amount of sugar that is customarily consumed is 8 g, which is 2 tsp. We further disagree that the amount of consumption data available for sugar was “limited,” as the sample size of data available met the criteria set forth in our methodology memo (Ref. 31). Therefore, we are finalizing the RACC for sugar as proposed.

We acknowledge that determining nutrition values on the label when measuring an odd number of teaspoons of sugar (such as 3 tsp, which equals 1½ servings) might be cumbersome for some consumers. Given the data showing a significant increase in consumption, however, we determined it was important for the RACC to reflect current consumption amounts.

The comment is correct in noting that we received no comments in favor of our changes to the RACC for sugar. We do not consider this relevant to our decision, however, as the consumption data is clear with respect to this product category.

To address the statement that updating the RACC for sugar would cause consumers to view the larger serving size as a recommended amount to eat, as discussed in comment 2, we intend to conduct nutrition education to help clarify that the meaning of “serving size” is not a recommended amount, but rather is based on an amount customarily consumed.

(Comment 63) Raisins--One comment requested that we add a separate product category for raisins with an RACC of 28/30 g (1 oz). The comment stated that the existing RACC does not represent the quantity of raisins contained in individual packages typically purchased by consumers and, therefore, is not representative of the actual amount customarily consumed per eating occasion. The comment stated that mini raisins boxes are packaged in ½ oz (14.2 g) boxes and sold in bags of various quantities, primarily 12 or 14 minis per bag. The comment also stated that the larger individual snack size products are currently packaged in boxes that are 1 oz (28.3 g) and are sold in packages of six. The comment asserted that the two different individual unit sizes of 14.2 g and 28.3 g are both widely consumed and represent the predominant proportion of industry retail raisin sales to consumers for out-of-hand snacking. The comment requested a separate RACC for raisins that is in line with the amount of raisins that is in an individual package of raisins. The comment stated that multiple-serving raisin packages are a different category from other dried fruits and are consumed in different ways by different consumers.

(Response 63) We decline to establish a new product category for raisins. Raisins are currently under the product category “Dried” under the “Fruits and Fruit Juices” general category

with an RACC of 40 g. We group together like products with similar dietary usage so consumers can easily compare nutrient information between similar products. Raisins are comparable to other dried fruits such as cranberries and are used in similar ways (e.g., as an ingredient in cookies); other dried fruits, such as cranberries are also consumed as snacks (Ref. 26). It would not be helpful for a consumer if there was a different RACC for raisins than there was for similar products on the market.

RACCs are determined primarily using consumption data, and other factors we consider in grouping products include similarities in dietary usage and product characteristics. Package size, which is not consistent and can change over time, is not a factor we considered in determining RACCs (see § 101.12(a)).

(Comment 64) Spray type fats and oils--Several comments requested that we amend the RACC for the product category "spray types" in the general category "Fats and Oils." The comments noted that the current RACC for this product category is 0.25 g. The comments stated that cooking sprays have tiny serving sizes which allow them to make certain claims such as "zero calorie" or "fat free," even though they are essentially pure oil. One comment recognized that no intake data were available from NHANES at the time of the proposed rule, but referred to a survey of 15 people that found that consumers spray a pan for 1.6 seconds on average, with the range being 1 to 3 seconds, compared to the one second spray that is found on the label of a common brand of cooking spray oil (Ref). The comments requested that we increase the RACC for spray cooking oils to a 2-second spray so consumers have a better understanding of the calories and fat they are consuming.

(Response 64) We decline to make a change to the RACC for spray oils. There are no data available in NHANES that can be used to update the RACC for cooking spray oils. We also

have not identified any other information on consumption of cooking spray oils that we can use as a basis for determining a different RACC. Although one comment referred to a study that it conducted, the comment provided no information about the methodology used and included a small sample size of only 15 people; therefore, this information provides an insufficient basis on which to update the RACC. Additionally, we note that serving size is based on the amount an individual consumes. Spray oils are often used to prepare food for multiple individuals, so even if the typical spray is longer than one second, the amount consumed by each individual may be significantly less.

(Comment 65) Yogurt--Several comments supported the proposed changes to the RACC for yogurt. Some comments asked us to clarify that the proposed 170 g (6 oz) RACC for yogurt applies to all forms of “yogurt” (e.g., cup, drinkable, squeezable) that comply with our standard of identity for yogurt. The comments specifically wanted clarification that drinkable yogurts would be subject to the proposed 170 g (6 fl oz) yogurt RACC versus the 240 mL (8 fl oz) RACC for the “Milk, milk substitutes, and fruit based drink mixers (without alcohol) (e.g., drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)” product category. One comment stated that a product labeled as “drinkable yogurt” is “yogurt” and must, like cup yogurt, meet one of our standards of identity for yogurt. The comment stated that drinkable yogurts are produced, marketed, and used by consumers as food (not as beverages) and are fundamentally different in both form and use from fluid milk, milk-substitute beverages, and other milk-based drinks.

(Response 65) We agree that drinkable yogurt is more similar to other forms of yogurt than to milk beverages. Drinkable yogurt is a product that is consistent with the standard of identity for yogurt under 21 CFR 131.200 but that is more fluid than other forms of yogurt.

Therefore, we are clarifying that the new yogurt RACC applies to all forms of yogurt including drinkable yogurt.

E. Impact of Changes in RACCs on the Eligibility to Make Nutrient Content Claims and Health Claims

We stated in the proposed rule that we were aware that individual foods that currently meet the requirements for certain claims based on existing RACCs may potentially become ineligible to continue to bear such claims if their RACCs change. Also, we recognized that other regulatory requirements for nutrient content claims and health claims are considered on a per-RACC basis, and changes to the RACCs could affect the ability of foods to meet these requirements. We noted that changes in the eligibility to bear claims may be appropriate in light of the changes in the amounts of food being customarily consumed but that it would be difficult to fully understand any potential impacts of changes to the RACCs on the eligibility to bear claims until the rules for both serving sizes and updating the Nutrition Facts label are finalized. We invited comment on any concerns related to changes to current claims used on specific foods that will be affected if the serving size rule is finalized as proposed (79 FR 11989 at 12015 to 12016).

(Comment 66) We received a number of comments in response to our discussion on claim eligibility in the proposed rule agreeing with us that foods could potentially become ineligible to bear a claim based on changes to the RACCs. A number of these comments suggested that we consider potential impacts on claim eligibility and evaluate if resulting changes in eligibility assists consumers in constructing healthful diets. Some comments stated that any changes that will be needed to regulations for nutrient content claims (NCCs) and health claims should be coordinated with the changes to the Nutrition Facts label and serving sizes. A

few comments cited examples of specific issues that could affect the foods that the commenters produce. One such example indicated that foods with the terms “Healthy” or “Lean” in their brand name may become ineligible to bear such claims and could be considered misbranded if the products would continue to bear such claims. Another example discussed the changes to the RACCs that make the RACCs different between bulk and novelty ice cream products and noted that such changes could make identical food products, but of different sizes, unable to bear the same claims. One example discussed changes to the RACC of confections and noted that because of the smaller proposed RACC, some confections would become subject to the NCC criteria for foods with small RACCs and become ineligible to bear some claims.

(Response 66) As we discussed in the proposed rule, we anticipate that there may be changes needed with regard to claims based on the new and updated regulations for Nutrition Facts and serving sizes. We agree with the comments that suggested that we evaluate claim regulations and any change to eligibility for claims. Changes to nutrition labeling is a step-wise process, and all changes to Nutrition Facts and serving sizes need to become final before we can determine any and all necessary changes to claim regulations. Because it is prudent for us to be fully aware of all final and official changes to the RACCs (and to the information in Nutrition Facts) before determining the scope of all of the changes needed to claim regulations, we are not publishing rules updating claim regulations simultaneously with the publication of the rules for serving sizes and Nutrition Facts. With the publication of this final rule (and the publication of the Nutrition Facts final rule, we can assess the impacts of all of the updates on claim eligibility.

We intend to consider in a future rulemaking issues such as whether any changes in eligibility for claims would assist consumers in constructing healthy diets and whether the criteria for claims remain appropriate. However, as we noted in the proposed rule, changes in

the eligibility to bear claims may be appropriate for some foods (79 FR 11989 at 12016).

Reformulation of some foods in line with current dietary recommendations may be expected in order to continue to bear claims. Manufacturers will have some time to make necessary changes before the compliance dates for the final rules on serving size and Nutrition Facts. This time will allow manufacturers to update food labels to come into compliance with the new regulations for serving size and Nutrition Facts, and it also allows time to discontinue use of individual voluntary claims that the labeling of certain products may no longer be eligible to make. The time will also allow us to evaluate the existing claim regulations and publish, in a separate rulemaking, any amendments to those claim regulations.

(Comment 67) One comment regarding the changes in the definition of a single-serving container and a product's ability to qualify for "free" claims stated that beverages that are routinely sold in single-serving containers for which the labeled serving is less than the RACC may no longer be able to make a calorie "free" or other "free" claims, even though the caloric or other nutrient content may be trivial in those particular single-serving packages. The comment said this outcome may occur because "free" claims are based on the nutrient content for both the labeled serving and the RACC. The comment gave the example of certain energy drink products that are commonly sold in 8 oz, single-serving containers. The comment asserted that the caloric content of these below-RACC, single-serving beverages is insignificant, which supports a calorie-free claim. However, 12 ozs of the product would contain just enough calories to preclude a calorie-free claim. Consequently, even though the single-serving product would not contain any more calories than before the RACCs would be updated, the small, single-serving beverage would be precluded from bearing a calorie-free claim because of the combined effect of

the proposed RACC and the requirement that calorie-free claims must be based on both per-labeled-serving and per-RACC nutrient content.

(Response 67) When we established “free” claims, we decided to make the basis of the claim on a per-RACC and per-labeled-serving basis (56 FR 60421 and 58 FR 2302). When we developed our general principles on nutrient content claims, we concluded that it would be misleading to allow certain claims to be based only on the RACC, particularly with single-serving containers, since the consumer would be expected to consume the entire labeled serving size. Likewise, we concluded that it would be misleading to allow claims based only on the labeled serving size. This decision was made to prevent potentially misleading claims and to provide a level field for industry. Since that time, consumption patterns have changed so that the RACC for some beverages has increased from 8 oz to 12 oz. Because the consumption amount has increased for certain beverages, such products for which the RACC has increased may appropriately no longer be able to make “free” claims. As noted previously, we intend to consider in a future rulemaking issues such as whether any changes in eligibility for claims would assist consumers in constructing healthy diets and whether the criteria for claims remain appropriate.

F. Establishing a New Serving Size for Breath Mints

In the serving size proposed rule, we proposed to establish a new serving size of “1 unit” for breath mints while maintaining the current reference amount of 2 g for the product category “Hard candies, breath mints.” We proposed this action in response to a petition that suggested the appropriate serving size for small breath mints should be “one mint” instead of the number of pieces that is closest to the 2 g RACC. The petitioner had also requested that a separate product

category, having an RACC of 0.5 g, should be established for small breath mints weighing 0.5 g or less.

We received one comment that supported a “1-unit” serving size for breath mints and no comments that addressed changing the RACC for breath mints. As mentioned in the serving size proposed rule (79 FR 11989 at 12016), we have determined through our analysis of two large commercial databases that 2 g remains an appropriate RACC for the product category “Hard candies, breath mints.” Further, because only a limited number of small breath mint products are commercially available, establishing a separate product category for small breath mints weighing 0.5 g or less, as the petitioner requested, is not warranted. Therefore, we will keep 2 g as the single reference amount for the “Hard candies, breath mints” product category, which includes breath mints of all sizes. However, we will now require that the label statement for the serving size of all breath mints be 1 unit, rather than declaring the serving size in terms of the number of mints closest to the 2 g RACC. We have indicated this in table 2 of § 101.12(b) by changing footnote 8 (formerly footnote 9) to state, in part, “Label serving size of ice cream cones, eggs, and breath mints of all sizes will be 1 unit.”

G. Technical Amendments

1. Rounding Rules for Products That Have More Than Five Servings and the Number of Servings Falls Exactly Between Two Values

In the serving size proposed rule (79 FR 11989) we proposed to add the following to § 101.9(b)(8)(i): “For containers that contain greater than 5 servings, if the number of servings determined from the procedures provided in this section falls exactly halfway between two allowable declarations, the manufacturer must round the number of servings up to the nearest incremental size.” We made this proposal to provide information to manufacturers who have

products that contain five or more servings to round the number of servings up when the number of servings falls exactly between two values.

We received no comments on this topic but are not finalizing the amendment as proposed. Standard rounding rules require numbers that fall exactly half way between two declarations to be rounded up to the nearest incremental size. This rule applies to all provisions where rounding is required and is not unique to rounding required for containers that contain greater than 5 servings. Because this proposed addition to § 101.9(b)(8)(i) is unnecessary, we are not finalizing the proposed amendment.

2. Options for When the Number of Servings per Container Varies

In the serving size proposed rule (79 FR 11989) we proposed to amend § 101.9(b)(8)(iii) by: (1) Defining “random-weight products” and (2) eliminating the wording that specifies that the nutrition information is based on the reference amount expressed in ounces. The proposed rule would define random-weight products as “foods such as cheeses that are sold as random weights that vary in size, such that the net contents for different containers would vary.”

We received no comments on this topic, and will finalize the amendment as proposed. We are also amending the final sentence of this paragraph to read “in parentheses” rather than “in parenthesis.”

3. Minor Corrections to General and Product Category Names

In the serving size proposed rule (79 FR 11989) we proposed to make minor changes to the names of certain general categories and product categories to clarify the products contained in the category, and to correct minor errors in these categories.

We received no comments on this topic, and will make these corrections in table 2 in § 101.12(b).

4. Minor Changes to Footnotes

In the serving size proposed rule (79 FR 11989) we proposed to remove footnote 4 from table 1 in § 101.12(b) to provide clearer guidance on the types of products that can be included in the product categories listed in the tables. We further proposed to renumber footnote 5 as footnote 4 and revise it by removing the first sentence and replacing it with the following: “The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products.” In table 2 we proposed to remove footnote 4 and renumber the remaining footnotes. We further proposed to revise renumbered footnote 4 by removing the first sentence and replacing it with the following: “The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products.” We also proposed to revise renumbered footnote 5 to include the sentence, “The serving size for fruitcake is 1 ½ ounces”; to add renumbered footnote 10 as a superscript to the word “pimento” in the “Vegetables, primarily used for garnish or flavor, e.g., pimento, parsley, fresh or dried)” product category; and to revise renumbered footnote 12 to state, “For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR 101) Code of Federal Regulations.”

We received no comments to these minor technical amendments and will make the changes in tables 1 and 2 in § 101.12(b).

In addition to the changes to various footnotes proposed in the proposed rule, we are making several additional technical amendments to table 2 by adding language to footnote 1 explaining that the values have been updated with data from various NHANES surveys, adding renumbered footnote 10 to the product category “Fruits for garnish or flavor, e.g., maraschino

cherries,” removing the “(b)” from the Code of Federal Regulations citation “101.9(b)(j)(11)” in renumbered footnote 11, and revising renumbered footnote 12 to state, “For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR 101) Code of Federal Regulations.”

5. Minor Changes to Table 1 in § 101.12(b)

In the serving size proposed rule (79 FR 11989) we proposed to change the title of table 1 from “Reference Amounts Customarily Consumed Per Eating Occasion: Infant and Toddler Foods” to “Reference Amounts Customarily Consumed Per Eating Occasion: Foods for Infants and Young Children 1 through 3 years of age.” We also proposed to make other conforming changes in the product category names, by changing the product category name “Dinners, stews or soups for toddlers, ready-to-serve” to “Dinners, stews or soups for young children, ready-to-serve,” the product category name “Fruits for toddlers, ready-to-serve” to “Fruits for young children, ready-to-serve,” and the product category name “Vegetables for toddlers, ready-to-serve” to “Vegetables for young children, ready-to-serve.”

We received no comments to these minor technical amendments and will make the changes in table 1 in § 101.12(b).

6. Minor Changes to Table 2 in § 101.12(b)

In the serving size proposed rule (79 FR 11989) we proposed to make some editorial changes to the product category names.

We received no comments to these minor technical amendments and will make the changes in table 2 in § 101.12(b).

7. Reference Amounts for Products That Require Further Preparation

In the serving size proposed rule (79 FR 11989), we proposed to amend § 101.12(c) to change the definition of the reference amount for products that require further preparation in which the entire contents of the package are used to prepare one large discrete unit usually divided for consumption.

We received no comments on this topic, and will finalize this amendment as proposed.

8. Reference Amount for Combined Products Consisting of Two or More Separate Foods That Are Packaged Together and Are Intended To Be Eaten Together and That Have No Reference Amount for the Combined Product

Section 101.12(f) establishes the approach for determining the reference amount for combined products consisting of two or more separate foods, packaged together and intended to be eaten together, that have no established reference amount in the tables for the combined product. In the serving size proposed rule (79 FR 11989) we proposed to amend § 101.9(f)(1) and (2) to change the definition of the RACC for these products consisting of two or more separate foods, packaged together and intended to be eaten together, so that it will not affect the serving size declaration on the label.

We received no comments on this topic, and will finalize the amendment as proposed.

9. Reference Amounts for Varieties or Assortments of Foods in Gift Packages That Have No Appropriate Reference Amount

Section 101.9(h)(3)(ii) establishes the procedure for determining the serving size for varieties or assortments of foods in gift packages when there is no appropriate reference amount. The current language in § 101.9(h)(3)(ii) states that 8 fl ozs may be used as the standard serving size for beverage varieties or assortments in gift packages. Because we are amending the

RACCs for some beverages, we proposed conforming amendments to this section to state that 12 fl oz should be used as the standard serving size for beverages, except that the standard serving size for milk, fruit juices, nectars, and fruit drinks will be based on 8 fl ozs.

We received no comments on this topic, and will finalize the amendment as proposed, with minor edits for clarity.

IV. Effective and Compliance Dates

In the preamble of the proposed rule (79 FR 11989 at 12019), we proposed that any final rule resulting from this rulemaking, as well as any final rule resulting from the proposed rule entitled “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (the Nutrition Facts proposed rule), would become effective 60 days after the date of the final rule’s publication in the Federal Register. We also proposed that any final rule that resulted would have a compliance date that would be 2 years after the effective date (79 FR 11989 at 12019). We explained that industry might need some time to analyze products for which there may be new mandatory nutrient declarations, make any required changes to the Nutrition Facts label (which may be coordinated with other planned label changes), review and update records of product labels, and print new labels.

After considering comments submitted to the docket for the Nutrition Facts proposed rule regarding the effective and compliance dates, we have maintained the compliance date of 2 years after the effective date, except that for manufacturers with less than \$10 million in annual food sales, we are providing a compliance date of 3 years after the effective date. Comments to the Nutrition Facts proposed rule emphasized the rule’s potential impact on small businesses. We agree that the impacts to smaller businesses may be more substantial than those on larger businesses; thus, for manufacturers with less than \$10 million in annual food sales, the

compliance date will be July 26, 2019. Using Nielsen data, we estimate that manufacturers with less than \$10 million in annual food sales constitute approximately 95 percent of all food manufacturers and market 48 percent of food UPCs.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(i) and (k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We are publishing two final rules on nutrition labeling in the Federal Register. We have developed a comprehensive Regulatory Impact Analysis (RIA) that assesses the impacts of the two final nutrition labeling rules taken together. We believe that the final rules on nutrition labeling, taken as a whole, are an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Additional costs per entity from the final rules are small, but not negligible, and as a result we find that the final rules on nutrition

labeling, taken as a whole, will have a significant economic impact on a substantial number of small entities.

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

The full analysis of economic impacts for the final rules on nutrition labeling is available in the docket for this final rule (Ref. 35) and at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/>.

VII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in this section with an estimate of the annual third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Third-Party Disclosure Requirements for Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating,

Modifying and Establishing Certain RACCs; Serving Size for Breath Mints; and Technical Amendments

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

Description: In major part, this final rule revises §§ 101.9 and 101.12 to: (1) Amend the definition of a single serving, (2) require a second column of nutrition information per package for products that contain at least 200 and up to and including 300 percent of the applicable RACCs, as well as per unit for discrete units in multiserving packages in which each unit contains at least 200 percent and up to and including 300 percent of the applicable RACCs, (3) update, modify, and establish RACCs for certain food products, (4) make several technical amendments to the regulations for serving sizes, and (5) change the label serving size for breath mints to “1 unit.” These revisions, in many instances, will require changes to the nutrition information that is presented on the Nutrition Facts label of retail food products. Preexisting §§ 101.9 and 101.12 are approved by OMB in accordance with the PRA under OMB control number 0910-0381. This final rule will modify the information collection associated with preexisting §§ 101.9 and 101.12 by adding to the burden associated with the collection by requiring the following manufacturers to make changes to their product labels: Those whose retail food products are labeled with a serving size that is inconsistent with the provisions of the final rule, and those whose retail food products would be required to use dual-column labeling.² The nutrient information disclosed on labels of retail food products is necessary to inform purchasers of the nutritional value of the food.

² Included in this burden are the labeling costs that result from changes in the eligibility to bear nutrient content claims or health claims (e.g., the cost of removing a claim from labeling or adding a required disclaimer).

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

Table 1.--Estimated Annual Third Party Disclosure Burden¹

| 21 CFR Section | No. of Respondents | No. of Disclosures per Respondent | Total Annual Disclosures | Average Burden per Disclosure | Total Hours | Total Capital Costs (in billions of 2014\$) |
|---|--------------------|-----------------------------------|--------------------------|-------------------------------|-------------|---|
| 101.9 and 101.12 | 13,452 | 25 | 336,300 | 2 | 672,600 | \$1.00 |
| Total Initial Hours and Capital Costs | | | | | 672,600 | \$1.00 |
| New Products | 500 | 1 | 500 | 2 | 1,000 | \$0.01 |
| Total Recurring Hours and Capital Costs | | | | | 1,000 | \$0.01 |
| Total Burden Hours and Capital Costs | | | | | 673,600 | \$1.01 |

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

Under §§ 101.9 and 101.12, some manufacturers of retail food products would need to make a labeling change to modify the serving sizes and other nutrition information based on changes to what products may be or are required to be labeled as a single serving or based on updated, modified, or established RACCs. Additionally, some manufacturers would need to change their product labels to add a second column of nutrition information per package or per discrete unit as part of the Nutrition Facts label. The third-party disclosure burden consists of the setup time required to design a revised label and incorporate it into the manufacturing process. The third-party disclosure burden for this final rule is estimated in table 1.

Based upon our knowledge of food labeling, we estimate that the affected manufacturers would require 2 hours per product to modify the label's Nutrition Facts panel. We estimate that it would take an affected manufacturer 1 hour to review a label to assess how to bring it into compliance with the requirements of this final rule. Each label redesign would require an estimated 1 additional hour per UPC, for a total of 2 hours per UPC.

We estimate that about 13,452 manufacturers would initially be affected by this final rule and that about 336,300 products would initially be required to be relabeled, for an average of 25 (336,300/13,452) products per respondent. The total initial third-party disclosure burden of 672,600 hours is reported in table 1. The final column of table 1 gives the estimated initial

capital cost of the relabeling associated with this final rule. Based on the RIA, we estimate the initial capital cost to be approximately \$1 billion (2014\$).

This final rule generates recurring burdens related to the requirement that some manufacturers undertake an extensive label change due to the effect of the changed definition of a single-serving container on the permissibility of certain health and nutrient content claims and also to the requirement that some manufacturers undertake a major redesign of their labels to include a Nutrition Facts Panel that had not previously been required.³ We estimate that about 500 new products would be affected by these requirements each year, and that the required third party disclosure burden would be 2 hours per product, for an annual recurring third party disclosure burden of 1,000 hours. Based on the RIA, we estimate the annual recurring capital cost to be approximately \$0.01 billion (2014\$).

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

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

Before the effective date of this final rule, we will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule.

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

³ This final rule does not otherwise generate any recurring burdens because establishments must already print packaging for food products as part of normal business practices and must disclose required nutrition and serving size information under NLEA.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to “construe... a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”

Section 403A of the FD&C Act (21 U.S.C. 343-1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that “... no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce... (4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q) [of the FD&C Act]....”

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the NLEA).

This final rule will create requirements that fall within the scope of section 403A(a) of the FD&C Act.

IX. References

The following references are on display in FDA’s Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>.

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33. Henderson, C., Memorandum to File, "Sample of Ice Cream Scoops Available to Consumers from National Retailers" May 16, 2016.

34. Park, Y., Memorandum to the file, List of products for each product category, October 8, 1992.

35. FDA, “Regulatory Impact Analysis for Final Rules on Food Labeling: Revision of the Nutrition and Supplement Facts Labels (Docket No. FDA-2012-N-1210 and Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying and Establishing Certain RACCs; Serving Size for Breath Mints; and Technical Amendments (Docket No. FDA-2004-N-0258 (formerly Docket No. 2004N-0456),” 2016.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and record keeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101--FOOD LABELING

1. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. In § 101.9:

a. Revise paragraph (b)(2)(i)(D);

b. Remove paragraph (b)(2)(i)(E) and redesignate paragraphs (b)(2)(i)(F) through (I) as paragraphs (b)(2)(i)(E) through (H) respectively;

c. Revise paragraphs (b)(6), (b)(8)(iii), and (b)(10)(ii);

d. Add paragraph (b)(12); and

e. Revise paragraph (h)(3)(ii).

The revisions and addition read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(D) If a unit weighs at least 200 percent and up to and including 300 percent of the applicable reference amount, the serving size shall be the amount that approximates the reference amount. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving size, the manufacturer shall provide a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per individual unit. The first column would be based on the serving size for the product and the second column would be based on the individual unit. The exemptions in paragraphs (b)(12)(i)(A), (B), and (C) of this section apply to this provision.

* * * * *

(6) A product that is packaged and sold individually that contains less than 200 percent of the applicable reference amount must be considered to be a single-serving container, and the entire content of the product must be labeled as one serving. In addition to providing a column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values per serving, for a product that is packaged and sold individually that contains more than 150 percent and less than 200 percent of the applicable reference amount, the Nutrition Facts label may voluntarily provide, to the left of the column that provides nutrition information per container (i.e., per serving), an additional column that lists the quantitative amounts and percent Daily Values per common household measure that most closely approximates the reference amount.

* * * * *

(8) * * *

(iii) For random weight products, manufacturers may declare “varied” for the number of servings per container provided the nutrition information is based on the reference amount expressed in the appropriate household measure based on the hierarchy described in paragraph (b)(5) of this section. 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. The manufacturer may provide the typical number of servings in parentheses following the “varied” statement.

* * * * *

(10) * * *

(ii) Per one unit if the serving size of a product in discrete units is more than 1 unit.

* * * * *

(12)(i) Products that are packaged and sold individually and that contain at least 200 percent and up to and including 300 percent of the applicable reference amount must provide an additional column within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values for the entire package, as well as a column listing the quantitative amounts and percent Daily Values for a serving that is less than the entire package (i.e., the serving size derived from the reference amount). The first column would be based on the serving size for the product and the second column would be based on the entire contents of the package.

(A) This provision does not apply to products that meet the requirements to use the tabular format in paragraph (j)(13)(ii)(A)(1) of this section or to products that meet the requirements to use the linear format in paragraph (j)(13)(ii)(A)(2) of this section.

(B) This provision does not apply to raw fruits, vegetables, and seafood for which voluntary nutrition labeling is provided in the product labeling or advertising or when claims are made about the product.

(C) This provision does not apply to products that require further preparation and provide an additional column of nutrition information under paragraph (e) of this section, to products that are commonly consumed in combination with another food and provide an additional column of nutrition information under paragraph (e) of this section, to products that provide an additional column of nutrition information for two or more groups for which RDIs are established (e.g., both infants and children less than 4 years of age), to popcorn products that provide an additional column of nutrition information per 1 cup popped popcorn, or to varied-weight products covered under paragraph (b)(8)(iii) of this section.

(ii) When a nutrient content claim or health claim is made on the label of a product that uses a dual column as required in paragraph (b)(2)(i)(D) or (b)(12)(i) of this section, the claim

must be followed by a statement that sets forth the basis on which the claim is made, except that the statement is not required for products when the nutrient that is the subject of the claim meets the criteria for the claim based on the reference amount for the product and the entire container or the unit amount. When a nutrient content claim is made, the statement must express that the claim refers to the amount of the nutrient per serving (e.g., “good source of calcium per serving” or “per X [insert unit]_ serving”) or per reference amount (e.g., “good source of calcium per [insert reference amount (e.g., per 8 ounces)]), as required based on § 101.12(g). When a health claim is made, the statement shall be “A serving of _ ounces of this product conforms to such a diet.”

* * * * *

(h) * * *

(3) * * *

(ii) In the absence of a reference amount customarily consumed in § 101.12(b) that is appropriate for the variety or assortment of foods in a gift package, the following may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph: 1 ounce for solid foods; 2 fluid ounces for nonbeverage liquids (e.g., syrups); 8 ounces for beverages that consist of milk and fruit juices, nectars and fruit drinks; and 12 fluid ounces for other beverages. However, the reference amounts customarily consumed in § 101.12(b) shall be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

* * * * *

3. In § 101.12:

a. In paragraph (b), revise tables 1 and 2;

- b. Revise paragraphs (c) and (f)(1);
- c. Remove paragraph (f)(2) and redesignate paragraph (f)(3) as paragraph (f)(2); and
- d. Revise newly redesignated paragraph (f)(2).

The revisions read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

Table 1.--Reference Amounts Customarily Consumed Per Eating Occasion: Foods for Infants and Young Children 1 Through 3 Years of Age^{1, 2, 3}

| Product Category | Reference Amount | Label Statement ⁴ |
|---|---|--|
| Cereals, dry instant | 15 g | _ cup (_ g) |
| Cereals, prepared, ready-to-serve | 110 g | _ cup(s) (_ g) |
| Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts | 7 g for infants and 20 g for young children (1 through 3 years of age) for ready-to-eat cereals; 7 g for all others | _ cup(s) (_ g) for ready-to-eat cereals; piece(s) (_ g) for others |
| Dinners, deserts, fruits, vegetables or soups, dry mix | 15 g | _ tbsp(s) (_ g); _ cup(s) (_ g) |
| Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type | 110 g | _ cup(s) (_ g); cup(s) (_ mL) |
| Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type | 110 g | _ cup(s) (_ g); cup(s) (_ mL) |
| Dinners, stews or soups for young children, ready-to-serve | 170 g | _ cup(s) (_ g); cup(s) (_ mL) |
| Fruits for young children, ready-to-serve | 125 g | _ cup(s) (_ g) |
| Vegetables for young children, ready-to-serve | 70 g | _ cup(s) (_ g) |
| Eggs/egg yolks, ready-to serve | 55 g | _ cup(s) (_ g) |
| Juices all varieties | 120 mL | 4 fl oz (120 mL) |

¹These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture. We further considered data from the National Health and Nutrition Examination Survey, 2003-2004, 2005-2006, and 2007-2008 conducted by the Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services.

²Unless otherwise noted in the reference amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (e.g., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

³Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

⁴The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

Table 2.--Reference Amounts Customarily Consumed Per Eating Occasion: General Food Supply ^{1,2,3}

| Product Category | Reference Amount | Label Statement ⁴ |
|--|------------------|--|
| Bakery Products: | | |
| Bagels, toaster pastries, muffins (excluding English muffins) | 110 g | _ piece(s) (_ g) |
| Biscuits, croissants, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies, scones, crumpets, English muffins | 55 g | _ piece(s) (_ g) |
| Breads (excluding sweet quick type), rolls | 50 g | _ piece(s) (_ g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/_ inch slice) for unsliced bread |
| Bread sticks--see crackers | | |
| Toaster pastries--see bagels, toaster pastries, muffins (excluding English muffins) | | |
| Brownies | 40 g | _ piece(s) (_ g) for distinct pieces; fractional slice (_ g) for bulk |
| Cakes, heavyweight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations) ⁵ | 125 g | _ piece(s) (_ g) for distinct pieces (e.g., sliced or individually packaged products); _ fractional slice (_ g) for large discrete units |
| Cakes, mediumweight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables or any of these combinations; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff) ⁶ | 80 g | _ piece(s) (_ g) for distinct pieces (e.g., cupcake); _ fractional slice (_ g) for large discrete units |
| Cakes, lightweight (angel food, chiffon, or sponge cake without icing or filling) ⁷ | 55 g | _ piece(s) (_ g) for distinct pieces (e.g., sliced or individually packaged products); _ fractional slice (_ g) for large discrete units |

| | | |
|--|--|---|
| Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads | 55 g | _ piece(s) (_ g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56 g/visual unit of measure) for bulk products (e.g., unsliced bread) |
| Cookies | 30 g | _ piece(s) (_ g) |
| Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones ⁸ | 15 g | _ piece(s) (_ g) |
| Crackers that are usually used as snacks | 30 g | _ piece(s) (_ g) |
| Croutons | 7 g | _ tbsp(s) (_ g); _ cup(s) (_ g); _ piece(s) (_ g) for large pieces |
| Eggroll, dumpling, wonton, or potsticker wrappers | 20 g | _ sheet (_ g); wrapper (_ g) |
| French toast, crepes, pancakes, variety mixes | 110 g prepared for French toast, crepes, and pancakes; 40 g dry mix for variety mixes | _ piece(s) (_ g); _ cup(s) (_ g) for dry mix |
| Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars | 40 g | _ piece(s) (_ g) |
| Ice cream cones--see crackers | | |
| Pies, cobblers, fruit crisps, turnovers, other pastries | 125 g | _ piece(s) (_ g) for distinct pieces; _ fractional slice (_ g) for large discrete units |
| Pie crust, pie shells, pastry sheets, (e.g., phyllo, puff pastry sheets) | the allowable declaration closest to an 8 square inch surface area | _ fractional slice(s) (_ g) for large discrete units; _ shells (_ g); _ fractional _ sheet(s) (_ g) for distinct pieces (e.g., Pastry sheet). |
| Pizza crust | 55 g | _ fractional slice (_ g) |
| Taco shells, hard | 30 g | _ shell(s) (_ g) |
| Waffles | 85 g | _ piece(s) (_ g) |
| Beverages: | | |
| Carbonated and noncarbonated beverages, wine coolers, water | 360 mL | 12 fl oz (360 mL) |
| Coffee or tea, flavored and sweetened | 360 mL prepared | 12 fl oz (360 mL) |
| Cereals and Other Grain Products: | | |
| Breakfast cereals (hot cereal type), hominy grits | 1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal | _ cup(s) (_ g) |
| Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains | 15 g | _ cup(s) (_ g) |
| Breakfast cereals, ready-to-eat, weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g | 40 g | _ cup(s) (_ g) |

| | | |
|--|--------------------------|---|
| Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types | 60 g | _ piece(s) (_ g) for large distinct pieces (e.g., biscuit type); _ cup(s) (_ g) for all others |
| Bran or wheat germ | 15 g | _ tbsp(s) (_ g); _ cup(s) (_ g) |
| Flours or cornmeal | 30 g | _ tbsp(s) (_ g); _ cup(s) (_ g) |
| Grains, e.g., rice, barley, plain | 140 g prepared; 45 g dry | _ cup(s) (_ g) |
| Pastas, plain | 140 g prepared; 55 g dry | _ cup(s) (_ g); _ piece(s) (_ g) for large pieces (e.g., large shells or lasagna noodles) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., spaghetti) |
| Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles | 25 g | _ cup(s) (_ g) |
| Starches, e.g., cornstarch, potato starch, tapioca, etc. | 10 g | _ tbsp (_ g) |
| Stuffing | 100 g | _ cup(s) (_ g) |
| Dairy Products and Substitutes: | | |
| Cheese, cottage | 110 g | _ cup (_ g) |
| Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese | 55 g | _ cup (_ g) |
| Cheese, grated hard, e.g., Parmesan, Romano | 5 g | _ tbsp (_ g) |
| Cheese, all others except those listed as separate categories-- includes cream cheese and cheese spread | 30 g | _ piece(s) (_ g) for distinct pieces; _ tbsp(s) (_ g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk |
| Cheese sauce--see sauce category | | |
| Cream or cream substitutes, fluid | 15 mL | 1 tbsp (15 mL) |
| Cream or cream substitutes, powder | 2 g | _ tsp (_ g) |
| Cream, half & half | 30 mL | 2 tbsp (30 mL) |
| Eggnog | 120 mL | ½ cup (120 mL); 4 fl oz (120 mL) |
| Milk, condensed, undiluted | 30 mL | 2 tbsp (30 mL) |
| Milk, evaporated, undiluted | 30 mL | 2 tbsp (30 mL) |
| Milk, milk-substitute beverages, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa, soy beverage | 240 mL | 1 cup (240 mL); 8 fl oz (240 mL) |
| Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes | 240 mL | 1 cup (240 mL); 8 fl oz (240 mL) |
| Sour cream | 30 g | _ tbsp (_ g) |
| Yogurt | 170 g | _ cup (_ g) |

| | | |
|--|--|---|
| Desserts: | | |
| Ice cream, frozen yogurt, sherbet, frozen flavored and sweetened ice and pops, frozen fruit juices: all types bulk and novelties (e.g., bars, sandwiches, cones, cups) | $\frac{2}{3}$ cup--includes the volume for coatings and wafers | $\frac{2}{3}$ cup (_ g), _ piece(s) (_ g) for individually wrapped or packaged products |
| Sundae | 1 cup | 1 cup (_ g) |
| Custards, gelatin, or pudding | $\frac{1}{2}$ cup prepared; amount to make $\frac{1}{2}$ cup prepared when dry | _ piece(s) (_ g) for distinct unit (e.g., individually packaged products); $\frac{1}{2}$ cup (_ g) for bulk |
| Dessert Toppings and Fillings: | | |
| Cake frostings or icings | 2 tbsp | _ tbsp(s) (_ g) |
| Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and non-dairy whipped toppings | 2 tbsp | 2 tbsp (_ g); 2 tbsp (30 mL) |
| Pie fillings | 85 g | _ cup(s) (_ g) |
| Egg and Egg Substitutes: | | |
| Egg mixtures, e.g., egg foo young, scrambled eggs, omelets | 110 g | _ piece(s) (_ g) for discrete pieces; _ cup(s) (_ g) |
| Eggs (all sizes) ⁸ | 50 g | 1 large, medium, etc. (_ g) |
| Egg whites, sugared eggs, sugared egg yolks, and egg substitutes (fresh, frozen, dried) | An amount to make 1 large (50 g) egg | _ cup(s) (_ g); _ cup(s) (_ mL) |
| Fats and Oils: | | |
| Butter, margarine, oil, shortening | 1 tbsp | 1 tbsp (_ g); 1 tbsp (15 mL) |
| Butter replacement, powder | 2 g | _ tsp(s) (_ g) |
| Dressings for salads | 30 g | _ tbsp (_ g); _ tbsp (_ mL) |
| Mayonnaise, sandwich spreads, mayonnaise-type dressings | 15 g | _ tbsp (_ g) |
| Spray types | 0.25 g | About _ seconds spray (_ g) |
| Fish, Shellfish, Game Meats, ⁹ and Meat or Poultry Substitutes: | | |
| Bacon substitutes, canned anchovies, ¹⁰ anchovy pastes, caviar | 15 g | _ piece(s) (_ g) for discrete pieces; _ tbsp(s) (_ g) for others |
| Dried, e.g., jerky | 30 g | _ piece(s) (_ g) |
| Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce | 140 g cooked | _ cup(s) (_ g); 5 oz (140 g/visual unit of measure) if not measurable by cup |
| Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake | 85 g cooked; 110 g uncooked ¹¹ | _ piece(s) (_ g) for discrete pieces; _ cup(s) (_ g); _ oz (_ g/visual unit of measure) if not measurable by cup ¹² |
| Fish, shellfish, or game meat ⁹ , canned ¹⁰ | 85 g | _ piece(s) (_ g) for discrete pieces; _ cup(s) (_ g); 3 oz (85 g/_ cup) for products that are difficult to measure the g weight of cup measure (e.g., tuna); 3 oz (85 g/_ pieces) for products that naturally vary in size (e.g., sardines) |

| | | |
|---|---|--|
| Substitute for luncheon meat, meat spreads, Canadian bacon, sausages, frankfurters, and seafood | 55 g | _ piece(s) (_ g) for distinct pieces (e.g., slices, links); _ cup(s) (_ g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product |
| Smoked or pickled fish, ¹⁰ shellfish, or game meat ⁹ ; fish or shellfish spread | 55 g | _ piece(s) (_ g) for distinct pieces (e.g., slices, links) or _ cup(s) (_ g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product |
| Substitutes for bacon bits--see Miscellaneous | | |
| Fruits and Fruit Juices: | | |
| Candied or pickled ¹⁰ | 30 g | _ piece(s) (_ g) |
| Dehydrated fruits--see snack category | | |
| Dried | 40 g | _ piece(s) (_ g) for large pieces (e.g., dates, figs, prunes); _ cup(s) (_ g) for small pieces (e.g., raisins) |
| Fruits for garnish or flavor, e.g., maraschino cherries ¹⁰ | 4 g | 1 cherry (_ g); _ piece(s) (_ g) |
| Fruit relishes, e.g., cranberry sauce, cranberry relish | 70 g | _ cup(s) (_ g) |
| Fruits used primarily as ingredients, avocado | 50 g | See footnote ¹² |
| Fruits used primarily as ingredients, others (cranberries, lemon, lime) | 50 g | _ piece(s) (_ g) for large fruits; _ cup(s) (_ g) for small fruits measurable by cup ¹² |
| Watermelon | 280 g | See footnote ¹² |
| All other fruits (except those listed as separate categories), fresh, canned or frozen | 140 g | _ piece(s) (_ g) for large pieces (e.g., strawberries, prunes, apricots, etc.); _ cup(s) (_ g) for small pieces (e.g., blueberries, raspberries, etc.) ¹² |
| Juices, nectars, fruit drinks | 240 mL | 8 fl oz (240 mL) |
| Juices used as ingredients, e.g., lemon juice, lime juice | 5 mL | 1 tsp (5 mL) |
| Legumes: | | |
| Tofu, ¹⁰ tempeh | 85 g | _ piece(s) (_ g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products |
| Beans, plain or in sauce | 130 g for beans in sauce or canned in liquid and refried beans prepared; 90 g for others prepared; 35 g dry | _ cup (_ g) |
| Miscellaneous: | | |
| Baking powder, baking soda, pectin | 0.6 g | _ tsp (_ g) |
| Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations | 1 tsp or 4 g if not measurable by teaspoon | _ piece(s) (_ g) for discrete pieces; 1 tsp (_ g) |

| | | |
|--|--|---|
| Batter mixes, bread crumbs | 30 g | _ tbsp(s) (_ g); _ cup(s) (_ g) |
| Chewing gum ⁸ | 3 g | _ piece(s) (_ g) |
| Cocoa powder, carob powder, unsweetened | 1 tbsp | 1 tbsp (_ g) |
| Cooking wine | 30 mL | 2 tbsp (30 mL) |
| Dietary supplements | The maximum amount recommended, as appropriate, on the label for consumption per eating occasion or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc. | _ tablet(s), _ capsules(s), _ packet(s), _ tsp(s) (_ g), etc. |
| Meat, poultry, and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes | Amount to make one reference amount of final dish | _ tsp(s) (_ g); _ tbsp(s) (_ g) |
| Milk, milk substitute, and fruit juice concentrates (without alcohol) (e.g., drink mixers, frozen fruit juice concentrate, sweetened cocoa powder) | Amount to make 240 mL drink (without ice) | _ fl oz (_ mL); _ tsp (_ g); tbsp (_ g) |
| Drink mixes (without alcohol): all other types (e.g., flavored syrups and powdered drink mixes) | Amount to make 360 mL drink (without ice) | _ fl oz (_ mL); _ tsp (_ g); _ tbsp (_ g) |
| Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits | 7 g | _ tbsp(s) (_ g) |
| Salt, salt substitutes, seasoning salts (e.g., garlic salt) | 1/4 tsp | 1/4 tsp (_ g); _ piece(s) (_ g) for discrete pieces (e.g., individually packaged products) |
| Seasoning oils and seasoning sauces (e.g., coconut concentrate, sesame oil, almond oil, chili oil, coconut oil, walnut oil) | 1 tbsp | 1 tbsp (_ g) |
| Seasoning pastes (e.g., garlic paste, ginger paste, curry paste, chili paste, miso paste), fresh or frozen | 1 tsp | 1 tsp (_ g) |
| Spices, herbs (other than dietary supplements) | 1/4 tsp or 0.5 g if not measurable by teaspoon | 1/4 tsp (_ g); _ piece(s) (_ g) if not measurable by teaspoons (e.g., bay leaf) |
| Mixed Dishes: | | |
| Appetizers, hors d'oeuvres, mini mixed dishes, e.g., mini bagel pizzas, breaded mozzarella sticks, egg rolls, dumplings, potstickers, wontons, mini quesadillas, mini quiches, mini sandwiches, mini pizza rolls, potato skins | 85 g, add 35 g for products with gravy or sauce topping | _ piece(s) (_ g) |

| | | |
|--|---|--|
| Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc. | 1 cup | 1 cup (_ g) |
| Not measurable with cup, e.g., burritos, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches | 140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce ¹³ | _ piece(s) (_ g) for discrete pieces; _ fractional slice (_ g) for large discrete units |
| Nuts and Seeds: | | |
| Nuts, seeds and mixtures, all types: Sliced, chopped, slivered, and whole | 30 g | _ piece(s) (_ g) for large pieces (e.g., unshelled nuts); _ tbsp(s) (_ g); _ cup(s) (_ g) for small pieces (e.g., peanuts, sunflower seeds) |
| Nut and seed butters, pastes, or creams | 2 tbsp | 2 tbsp (_ g) |
| Coconut, nut and seed flours | 15 g | _ tbsp(s) (_ g); _ cup (_ g) |
| Potatoes and Sweet Potatoes/Yams: | | |
| French fries, hash browns, skins, or pancakes | 70 g prepared; 85 g for frozen unprepared French fries | _ piece(s) (_ g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/_ pieces) for prepared fries; 3 oz (84 g/_ pieces) for unprepared fries |
| Mashed, candied, stuffed or with sauce | 140 g | _ piece(s) (_ g) for discrete pieces (e.g., stuffed potato); _ cup(s) (_ g) |
| Plain, fresh, canned, or frozen | 110 g for fresh or frozen; 125 g for vacuum packed; 160 g for canned in liquid | _ piece(s) (_ g) for discrete pieces; _ cup(s) (_ g) for sliced or chopped products |
| Salads: | | |
| Gelatin salad | 120 g | _ cup (_ g) |
| Pasta or potato salad | 140 g | _ cup(s) (_ g) |
| All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads | 100 g | _ cup(s) (_ g) |
| Sauces, Dips, Gravies, and Condiments: | | |
| Barbecue sauce, hollandaise sauce, tartar sauce, tomato chili sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa) | 2 tbsp | 2 tbsp (_ g); 2 tbsp (30 mL) |
| Major main entree sauces, e.g., spaghetti sauce | 125 g | _ cup (_ g); _ cup (_ mL) |
| Minor main entree sauces (e.g., pizza sauce, pesto sauce, Alfredo sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce | ¼ cup | ¼ cup (_ g); ¼ cup (60 mL) |

| | | |
|---|--|---|
| Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades | 1 tbsp | 1 tbsp (_ g); 1 tbsp (15 mL) |
| Minor condiments, e.g., horseradish, hot sauces, mustards, Worcestershire sauce | 1 tsp | 1 tsp (_ g); 1 tsp (5 mL) |
| Snacks: | | |
| All varieties, chips, pretzels, popcorn, extruded snacks, fruit and vegetable-based snacks (e.g., fruit chips), grain-based snack mixes | 30 g | _ cup (_ g) for small pieces (e.g., popcorn); _ piece(s) (_ g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28g/visual unit of measure) for bulk products (e.g., potato chips) |
| Soups: | | |
| All varieties | 245 g | _ cup (_ g); _ cup (_ mL) |
| Dry soup mixes, bouillon | Amount to make 245 g | _ cup (_ g); _ cup (_ mL) |
| Sugars and Sweets: | | |
| Baking candies (e.g., chips) | 15 g | _ piece(s) (_ g) for large pieces; _ tbsp(s) (_ g) for small pieces; ½ oz (14 g/visual unit of measure) for bulk products |
| After-dinner confectioneries | 10 g | _ piece(s) (_ g) |
| Hard candies, breath mints ⁸ | 2 g | _ piece(s) (_ g) |
| Hard candies, roll-type, mini-size in dispenser packages | 5 g | _ piece(s) (_ g) |
| Hard candies, others; powdered candies, liquid candies | 15 mL for liquid candies; 15 g for all others | _ piece(s) (_ g) for large pieces; _ tbsp(s) (_ g) for "mini-size" candies measurable by tablespoon; _ straw(s) (_ g) for powdered candies; _ wax bottle(s) (_ mL) for liquid candies; ½ oz (14 g/visual unit of measure) for bulk products |
| All other candies | 30 g | _ piece(s) (_ g); 1 oz (30 g/visual unit of measure) for bulk products |
| Confectioner's sugar | 30 g | _ cup (_ g) |
| Honey, jams, jellies, fruit butter, molasses, fruit pastes, fruit chutneys | 1 tbsp | 1 tbsp (_ g); 1 tbsp (15 mL) |
| Marshmallows | 30 g | _ cup(s) (_ g) for small pieces; _ piece(s) (_ g) for large pieces |
| Sugar | 8 g | _ tsp (_ g); _ piece(s) (_ g) for discrete pieces (e.g., sugar cubes, individually packaged products) |

| | | |
|--|--|--|
| Sugar substitutes | An amount equivalent to one reference amount for sugar in sweetness | _ tsp(s) (_ g) for solids; _ drop(s) (_ g) for liquid; _ piece(s) (_ g) (e.g., individually packaged products) |
| Syrups | 30 mL for all syrups | 2 tbsp (30 mL) |
| Vegetables: | | |
| Dried vegetables, dried tomatoes, sun-dried tomatoes, dried mushrooms, dried seaweed | 5 g, add 5 g for products packaged in oil | _ piece(s); 1/3 cup (_ g) |
| Dried seaweed sheets | 3 g | _ piece(s) (_ g); _ cup(s) (_ g) |
| Vegetables primarily used for garnish or flavor (e.g., pimento, ¹⁰ parsley, fresh or dried) | 4 g | _ piece(s) (_ g); _ tbsp(s) (_ g) for chopped products |
| Fresh or canned chili peppers, jalapeno peppers, other hot peppers, green onion | 30 g | _ piece(s) (_ g) ¹² ; _ tbsp(s) (_ g); _ cup(s) (_ g) for sliced or chopped products |
| All other vegetables without sauce: Fresh, canned, or frozen | 85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash | _ piece(s) (_ g) for large pieces (e.g., Brussels sprouts); _ cup(s) (_ g) for small pieces (e.g., cut corn, green peas); 3 oz (84 g/visual unit of measure) if not measurable by cup |
| All other vegetables with sauce: Fresh, canned, or frozen | 110 g | _ piece(s) (_ g) for large pieces (e.g., Brussels sprouts); _ cup(s) (_ g) for small pieces (e.g., cut corn, green peas); 4 oz (112 g/visual unit of measure) if not measurable by cup |
| Vegetable juice | 240 mL | 8 fl oz (240 mL) |
| Olives ¹⁰ | 15 g | _ piece(s) (_ g); _ tbsp(s) (_ g) for sliced products |
| Pickles and pickled vegetables, all types ¹⁰ | 30 g | 1 oz (28 g/visual unit of measure) |
| Pickle relishes | 15 g | _ tbsp (_ g) |
| Sprouts, all types: Fresh or canned | 1/4 cup | 1/4 cup (_ g) |
| Vegetable pastes, e.g., tomato paste | 30 g | _ tbsp (_ g) |
| Vegetable sauces or purees, e.g., tomato sauce, tomato puree | 60 g | _ cup (_ g); _ cup (_ mL) |

¹ These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977-1978 and the 1987-1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture and updated with data from the National Health and Nutrition Examination Survey, 2003-2004, 2005-2006 and 2007-2008 conducted by the Centers for Diseases Control and Prevention, in the Department of Health and Human Services.

² Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (e.g., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes, concentrates, dough, batter, fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

³ Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

⁴The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products. The term “piece” is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

⁵Includes cakes that weigh 10 g or more per cubic inch. The serving size for fruitcake is 1 ½ ounces.

⁶Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

⁷Includes cakes that weigh less than 4 g per cubic inch.

⁸Label serving size for ice cream cones, eggs, and breath mints of all sizes will be 1 unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be 1 unit.

⁹Animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

¹⁰If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (e.g., canned chopped clam in juice).

¹¹The reference amount for the uncooked form does not apply to raw fish in § 101.45 or to single-ingredient products that consist of fish or game meat as provided for in § 101.9(j)(11).

¹²For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices C and D to part 101 (21 CFR part 101) Code of Federal Regulations.

¹³Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) If a product requires further preparation, e.g., cooking or the addition of water or other ingredients, and if paragraph (b) of this section provides a reference amount for the product in the prepared form, but not the unprepared form, then the reference amount for the unprepared product must be the amount of the unprepared product required to make the reference amount for the prepared product as established in paragraph (b) of this section.

* * * * *

(f) * * *

(1) The reference amount for the combined product must be the reference amount, as established in paragraph (b) of this section, for the ingredient that is represented as the main ingredient (e.g., peanut butter, pancakes, cake) plus proportioned amounts of all minor ingredients.

(2) If the reference amounts are in compatible units, the weights or volumes must be summed (e.g., the reference amount for equal volumes of peanut butter and jelly for which

peanut butter is represented as the main ingredient would be 4 tablespoons (tbsp) (2 tbsp peanut butter plus 2 tbsp jelly)). If the reference amounts are in incompatible units, all amounts must be converted to weights and summed, e.g., the reference amount for pancakes and syrup would be 110 g (the reference amount for pancakes) plus the weight of the proportioned amount of syrup.

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Dated: May 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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