DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2004–N–0258 (Formerly Docket No. 2004N–0456)]

RIN 0910–AF23

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend the definition of a single-serving container; require dual-column labeling for certain containers; update and modify several reference amounts customarily consumed (RACCs or reference amounts); add several food products and food product categories to the reference amounts customarily consumed per eating occasion for the general food supply; amend the label serving size for breath mints; and make technical amendments to various aspects of the serving size regulations. These actions are being taken, in part, in response to recommendations of the 2003 FDA Obesity Working Group and FDA's recognition that portion sizes have changed since the original serving size regulations were published in 1993. This proposal also discusses six citizen petitions. The intended effect of this rulemaking is to provide consumers with more accurate and up-to-date information on serving sizes.

DATES: Submit either electronic or written comments on the proposed rule by June 2, 2014. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by April 2, 2014, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2004–N–0258 and/or RIN 0910–AF23, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2004–N–0258 and Regulatory Information Number 0910–AF23 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this proposed rule.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this proposed rule, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: With regard to the proposed rule: Cherisa Henderson, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–5429, *NutritionProgramStaff@fda.hhs.gov*.

With regard to the information collection: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Picard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@fda.hhs.gov*.

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Executive Summary

Purpose of the Proposed Rule

Need for the Proposed 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 re-evaluate 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 helping consumers maintain 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 proposes a number of changes to our regulations in §§ 101.9 and 101.12. In consideration of the new consumption data, this rule proposes to amend the reference amounts customarily consumed (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 proposes to amend some of the required procedures used to determine serving sizes, proposes to amend the definition of a single serving container, and also proposes to require 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 proposals in this rule are designed to ensure that serving sizes are based on current consumption data, as well as to provide consumers with information on the nutrition facts label, related to the serving size, that will help them maintain healthy dietary practices.

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 regulated by the Agency. 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 proposed rule. Additionally, we are relying on section 2(b)(1)(A) of 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 also 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 proposed 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 deemed 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 these authorities listed in this paragraph give us the authority to issue this proposed rule related to serving size labeling.

Summary of the Major Provisions of the Proposed Rule

Single-Serving Containers and Dual-Column Labeling

Over the last 20 years, evidence has accumulated demonstrating that container sizes can influence the amount of food consumed. For containers of certain sizes, consumers are likely to eat the entire container in one sitting. For other container sizes, consumers may consume the container in one sitting or may consume the container over multiple sittings or share the container contents with other consumers. To address containers that may be consumed in a single-eating occasion, FDA is proposing 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 that may be consumed in one or more sittings, or shared, FDA is proposing that containers that contain at least 200 percent and up to and including 400 percent of the RACC be labeled with dual-column labels that include a column of nutrition information within the Nutrition Facts label that lists the quantitative amounts and percent Daily Values (percent DVs) for the entire container, as well as the preexisting 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).

Changing the Reference Amounts Customarily Consumed (RACCs)

FDA 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, FDA has analyzed recent food consumption data

from the National Health and Nutrition Examination Surveys (NHANES) (2003–2008 surveys).[1] Generally, changes to the RACCs are proposed in this rule 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 are also considering 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 proposed rule.

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 rule proposes a number of technical amendments to help clarify the serving size requirements in these regulations.

Effective Date

We are proposing an effective date of 60 days after the date of the final rule's publication in the **Federal Register** with a compliance date 2 years after the effective date.

Costs and Benefits

We have developed one comprehensive preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule as well as the proposed rule entitled ''Food Labeling: Revision of the Nutrition and Supplement Facts Labels''. The PRIA analyzes the costs and benefits of both the major changes proposed by the rules (i.e., those proposals that would require the manufacturer to undertake a re-design of their label), as well as the minor changes proposed by the rules (i.e., those proposals that would not require a label re-design). The cumulative impact of these two nutrition labeling proposals, assuming a two-year compliance period and taken as a whole, is shown in the following table.

SUMMARY OF COSTS AND BENEFITS OVER 20 YEARS

[In billions of 2011 $]

	Benefits	Costs	Net benefits
Present Value (PV):			
3%	$31.4	$2.3	$29.1
7%	21.1	2.3	18.8
Annualized (3% PV Amount):			
3%	2.0	0.2	1.8
Annualized (7% PV Amount):			
7%	1.9	0.2	1.7

Notes: Compliance period is 24 months. Costs include relabeling and reformulation costs, which are one-time costs, as well as recordkeeping costs, which recur. Present values of relabeling and reformulation costs are equivalent at 3 or 7 percent because we conservatively assume that these one-time costs are incurred upon publication of the rule instead of at the end of the compliance period. Recordkeeping costs, because of their recurring nature, differ by discount rate; however, such costs comprise a very small percentage of total costs.

I. Background

A. The Serving Size Regulations

On November 8, 1990, the Nutrition Labeling and Education Act (the NLEA) was signed into law (Pub. L. 101–535). The NLEA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet. Section 403(q)(1)(A)(i) of the FD&C Act (21 U.S.C. 343(q)(1)(A)(i)) requires that most foods under FDA's jurisdiction bear nutrition information that provides a serving size that reflects the amount of food customarily consumed per eating occasion and is expressed in a common household measure appropriate to the food. Section 2(b)(1)(B) of the NLEA also required that we issue regulations that establish standards to define serving size.

To implement the serving size requirements of the NLEA, FDA conducted notice-and-comment rulemaking (56 FR 60394, November 27, 1991 (the 1991 serving size proposed rule), and 58 FR 2229, January 6, 1993 (the 1993 serving size final rule)). FDA also published technical amendments to the 1993 serving size final rule on August 18, 1993 (58 FR 44039) (the 1993 technical amendments). Consistent with the FD&C Act, the serving size regulations established standards to define ''serving size'' that are composed of two basic elements: (1) Reference amounts customarily consumed (RACCs or reference amounts) per eating occasion for specific food product categories; and (2) procedures for determining serving sizes for use on product labels derived from the RACCs. The second element was necessary because the RACCs are provided primarily in metric units (based on data from national food consumption surveys that are expressed in grams); however, the FD&C Act requires that serving sizes be expressed in common household measures that are appropriate to the particular food.

Section 101.9(b)(1) (§ 101.9(b)(1)) defines the term ''serving or serving size'' to mean an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

Section 101.12(a) (§ 101.12(a)) describes the general principles and factors that we considered in arriving at the RACCs. Among these principles, we sought to ensure that foods that have similar dietary usage, product

[1] Hereinafter referred to as the NHANES 2003–2008 surveys or NHANES 2003–2008 consumption data, as applicable.

characteristics, and customarily consumed amounts have a uniform reference amount customarily consumed (RACC or reference amount) so that consumers could make nutritional comparisons of similar products in the marketplace. In § 101.12(b), we established RACCs (upon which label serving sizes are to be determined) for 129 product categories representing the general food supply and 11 product categories of foods for infants and children 1 through 3 years of age.

The current RACCs represent the amount of food customarily consumed per eating occasion for each product category, and were derived primarily from data obtained from the 1977–1978 and 1987–1988 Nationwide Food Consumption Surveys (NFCS) conducted by the U.S. Department of Agriculture (USDA) (58 FR 2229 at 2236–2237). We reviewed food consumption data for the foods in each product category and considered three statistical estimates: The mean (average), the median (50th percentile), and the mode (the most frequent value). For the 1993 serving size final rule we followed the procedures discussed in the 1991 serving size proposed rule (56 FR 60394 at 60403–60406) and the general principles discussed in § 101.12, and determined the RACC that was most likely to represent the amount customarily consumed for each product category.

Section 101.9(b) establishes procedures for converting RACCs into appropriate label serving sizes. Section 101.9(b)(6) defines the criteria for products to be labeled as single-serving containers. Generally, products packaged and sold individually that contain less than 200 percent of the applicable RACC must currently be labeled as one serving. An exception to this rule occurs for products that contain more than 150 but less than 200 percent of the RACC and that have a RACC of 100 grams (g) or 100 milliliters (mL) or larger. In this case, the product may be labeled as one or two servings, at the manufacturer's discretion. For example, the RACC for carbonated beverages is 240 mL (i.e., 8 fluid (fl) ounces (oz)). Containers of carbonated beverages that are 360 mL (i.e., 12 fl oz, 150 percent of 240 mL) or less must be labeled as a single serving. Containers of carbonated beverages weighing more than 360 mL and less than 480 mL (i.e., more than 12 fl oz, 150 percent of 240 mL, and less than 16 fl oz, 200 percent of 240 mL) may be labeled as ''1 serving'' or as ''2 servings'' per container. For products packaged and sold individually that contain 200 percent or more of the RACC, the manufacturer may currently label the product as a single-serving if the entire content of the container can reasonably be consumed at a single-eating occasion (§ 101.9(b)(6)).

Under § 101.9(b)(11), manufacturers must provide a second column of nutrition information for products that are promoted on the label, labeling, or advertising for a use that differs in quantity from the RACC by 200 percent or greater from the use upon which the reference amount was based (e.g., liquid cream substitutes promoted for use with breakfast cereals). The second column of nutrition information is based on the amount customarily consumed in the promoted use.

Manufacturers may also voluntarily provide a second column of nutrition information per 100g or 100 mL, or per 1 oz or 1 fl oz of the food as ''packaged'' or ''purchased'' (§ 101.9(b)(10)(i)) and per cup popped for popcorn in a multi-serving container (§ 101.9(b)(10)(iii)). Additionally, manufacturers may voluntarily provide a second column of nutrition information on the Nutrition Facts label per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit (§ 101.9(b)(10)(ii)). For example, the RACC for muffins is currently 55 g. Under § 101.9(b)(10)(ii), if three muffins in a multi-serving container of six muffins weigh 18 g each, there are two options for the serving size declaration: (1) A label showing the serving size as ''3 muffins (55 g),'' with the Nutrition Facts label listing nutrition information per serving (i.e., 3 muffins); or (2) a label with the Nutrition Facts label listing again the nutrition information per serving (i.e., 3 muffins), but also with an additional column listing the nutrition information per ''1 muffin (18 g),'' which would be less than one serving.

Dual-column labeling may also be used to present nutrition information for two or more forms of the same food (e.g., both ''as purchased'' and ''as prepared'') under § 101.9(e). Additionally, if a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, under certain circumstances an additional column may be used to declare nutrition information on the basis of the food as ''consumed'' (§ 101.9(h)(4)). For example a dry ready-to-eat cereal may be described with one set of Percent Daily Values for the cereal as sold per ounce, and may use another for the cereal with milk (e.g., per ounce of cereal plus 1/2 cup of vitamin D fortified skim milk).

B. The Obesity Working Group

In August 2003, the Commissioner of Food and Drugs created the Obesity Working Group (OWG) and charged it to develop an action plan covering the critical dimensions of the obesity problem in America to help consumers lead healthier lives through better nutrition. The OWG was composed of professionals across FDA who provided a range of expertise in areas such as food labels, communication and education efforts, the role of industry and restaurants, and therapeutic interventions for obesity. A docket was established in July of 2003 (Docket No. FDA–2003–N–0161 (formerly Docket No. 2003N–0338)) (the ''Obesity docket'') to accept comments on obesity-related issues. The OWG's final report entitled ''Calories Count'' (the ''Calories Count'' report) centered on the scientific fact that weight control is primarily a function of the balance of calories eaten and calories expended; and therefore, focused on a calories count emphasis for FDA actions (Ref. 1).

A principal aspect of the Commissioner's charge was for the OWG to develop an approach for enhancing and improving the food label to help consumers prevent weight gain and reduce obesity. To address this issue, among other actions, the OWG recommended that we reexamine our serving size regulations by inviting comment on: (1) Whether to require food packages that can reasonably be consumed at one-eating occasion to declare the whole package as a single serving; (2) which, if any, RACCs of food categories need to be updated; and (3) whether to provide for comparative calorie claims for smaller portions of identical foods.

C. The Advance Notice of Proposed Rulemaking

On April 4, 2005, we published an advance notice of proposed rulemaking (ANPRM) (70 FR 17010) 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.'' The ANPRM was published in response to the ''Calories Count'' report. The ANPRM focused on the following topics, which are also discussed in this proposed rule: (1) Single-serving containers and dual-column labeling; (2) updating the RACCs; and (3) calorie comparison claims. We used the three topics of the ANPRM to structure this proposed rule.

1. Single-Serving Containers

The ANPRM invited comment on topics that originated, in large part, from the OWG's activities. Several comments submitted to the Obesity docket strongly opposed the practice of individually packaged foods that appear to be single-serving containers, declaring two or more servings on the label—such as certain sodas and snack packages. In 2003, we initiated eight focus groups around the country and showed them examples of labels of a 20 fl oz soda and an individually packaged large muffin. Focus group participants thought these products should be labeled as single-serving products (Ref. 1). Many participants (though not all) did understand that if the entire package of food is eaten, the number of servings should be multiplied by the amount of the nutrient of interest; though some participants made mistakes when trying to calculate the total amount of nutrients (Ref. 2) To address problems identified from focus groups, the ANPRM discussed amending the definition of a single-serving container in § 101.9(b)(6) and providing an additional column in the Nutrition Facts label that would list the nutrition information for the entire package in addition to a column listing multiple servings for the package (70 FR 17010 at 17012).

In the 1993 serving size final rule, we used the mean, median, and mode from food consumption surveys to determine the RACCs. In addition to these three statistical estimates (i.e., the mean, median, and mode), food consumption surveys allow calculation of intake estimates for individuals who eat a greater amount of food than average (e.g., those in the 90th and 95th percentiles). Because estimates can be calculated for individuals that eat a greater amount of food than average, in the ANPRM, we invited comment on whether the 90th and 95th percentiles could be used to determine the cutoff points at or below which nutrition information should be provided for the entire package (70 FR 17010 at 17013).

We also sought comment in the ANPRM on the potential effects of requiring that manufacturers list the nutrient content for the entire package for certain package sizes (70 FR 17010 at 17013).

2. Updating the RACCs

Because there is evidence that the U.S. population is eating larger portion sizes than it did in the 1970s and 1980s (Refs. 3, 4, 5, and 6), the OWG recommended that FDA determine whether to update the RACCs, and, if so, how to update the RACCs. The ANPRM recognized that changes to the RACCs, in most instances, would require changes to the serving size on products, which in turn would require changes to the nutrient values listed on the Nutrition Facts label (70 FR 17010 at 17012).

Even if consumers are consuming larger amounts, we do not want consumers to confuse the serving size on the food label (which the FD&C Act requires to be based on the amount customarily consumed) with an amount that dietary guidance documents, such as the Dietary Guidelines for Americans (Ref. 7), recommend for consumption. For example, if data show that consumers are drinking larger amounts of carbonated beverages, and we increase the RACC for such beverages, which will likely increase the amount of the serving size on the label, additional educational efforts may be needed to reinforce to consumers that a larger serving size on the container is not a ''recommended'' serving size. The ANPRM invited comment on how recent consumption data should factor into the determination of which, if any, RACCs should be updated [2] and what criteria should be used as the basis for change (70 FR 17010 at 17012). We also invited comment on how we could make serving size information on the Nutrition Facts label easier for consumers to use when deciding what foods and how much of these foods to eat (70 FR 17010 at 17012).

3. Comparison of Calories in Foods of Different Portion Sizes

As noted in the ''Calories Count'' report, the Federal Trade Commission had suggested that we consider ''allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes (Ref. 1).'' Our regulations discuss requirements to use certain characterizing terms to make comparative nutrient content claims (called ''relative claims'') that compare the level of nutrients in two foods, including calorie comparisons, and require that all such comparisons be based on a uniform amount of food, i.e., per RACC for individual foods or per 100 g for meals and main dishes (see 21 CFR Part 101, Subpart D, and § 101.13(j)). Section 101.13(j) also requires that such comparisons made in ''relative claims'' reflect actual nutrient differences in the same quantity of similar foods (e.g., ''Reduced calorie chocolate ice cream, 25 percent fewer calories than the leading brand of chocolate ice cream. The leading brand contains 150 calories per ½ cup serving. Our ice cream contains 100 calories per ½ cup serving'') or dissimilar foods within a product category that can be substituted for one another (e.g., ''Reduced sodium pretzels, 33 percent less sodium than the leading brand of potato chips. Our pretzels contain 105 mg of sodium per serving. The leading brand of potato chips contains 320 mg of sodium per serving). The nutrient content claim regulations do not specifically discuss claims that compare the amount of calories based on different sized portions of the same food product. However, FDA's regulations do allow certain statements in the label or labeling of a food product about the amount or percentage of a nutrient in the food (see § 101.13(i)). As noted in the ''Calories Count'' report, ''using the food label to promote consumption of smaller portions may have merit, particularly if consumers understand that: (1) The calorie reduction is solely a function of the reduction in portion size and, (2) the smaller portion size is actually less than what they usually consume.'' Thus, the ANPRM invited comment regarding the appropriateness of label claims based on the amount of calories in a specified portion of a product (i.e., the amount of food specified by the claim, e.g., one 15 g cookie) versus claims based on the RACC and specified in the labeled serving size of a product (i.e., the amount specified on the Nutrition Facts label (e.g., two 15 g cookies)) (70 FR 17010 at 17013).

4. Overview of Comments on the Advance Notice of Proposed Rulemaking

The ANPRM resulted in approximately 850 comments from health advocacy groups, industry, trade associations, consumer groups, individual consumers, government, health professionals, and academia. Not all of the comments received addressed the questions posed in the ANPRM, and many comments were outside the scope of the rulemaking. We discuss the comments within the scope of the ANPRM later in this proposed rule.

[2] We note that in this proposed rule, when we speak of ''updates to'' or ''updating'' the RACCs established in 1993, we are referring to amendments to RACCs for products that are currently listed in the tables in § 101.12(b), and for which the NHANES 2003–2008 consumption data showed a significant change in consumption (as discussed in the proposed amendments section, we have determined that an increase or decrease in consumption by at least 25 percent from the amount listed in the tables in § 101.12(b) would be considered a significant change).

D. Requests for Changes to Serving Size Requirements

This section describes the six citizen petitions, as well as other documentation related to requests for changes to serving size requirements and requests for dual column labeling that will be addressed, in part, in this proposed rule.

1. Requests To Modify and Establish Certain RACCs and Add Products to Product Categories

We have received several requests (Ref. 8), and six citizen petitions that are discussed in this document, to modify [3] the current RACCs for specific products that are already listed in the tables in § 101.12(b). We have also received several requests to establish [4] ''new'' RACCs for food products that are not listed in the tables in § 101.12(b) by adding ''new'' product categories to a general category or ''new'' products to a product category (Refs. 8, 9, and 10). We discuss these requests in sections II.D.3.b., II.D.6 and II.E.

2. Adding Products to the List of Products for Each Product Category

In the 1991 serving size proposed rule, we provided as a reference (Ref. 20 of the 1991 serving size proposed rule) an extensive list that manufacturers could use, which included examples of products for a given product category (Ref. 11). The List of Products for Each Product Category was updated in the 1993 serving size final rule and we stated that we would revise the list as necessary (58 FR 2229 at 2241) and that those who were not sure about which product category their specific products belong to should refer to the list or consult us (58 FR 2229 at 2291). Copies of the list are available from the Office of Nutrition, Labeling and Dietary Supplements, Food and Drug Administration 5100 Paint Branch Parkway, College Park, MD 20740. Separately from this rulemaking, we are planning to update the list and make it available as draft guidance after the publication of this proposed rule. If finalized, the guidance document would be made available on our Web site.

[3] We note that in this rule, when we speak of ''modify'' or ''modifying'' RACCs, we are referring to changes to existing 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 by at least 25 percent.

[4] We note that in this rule, when we speak of ''establish'' or ''establishing'' RACCs, we are referring to the addition of products (and assigning RACCs for such products) that are not already listed in the tables in § 101.12(b).

3. Citizen Petitions

a. Petition for Food and Beverages Sold in Single-Serving Containers

On October 29, 2004, the Center for Science in the Public Interest (CSPI) submitted a citizen petition (Docket No. FDA–2004–P–0210, formerly Docket No. 2004P–0483) (the CSPI petition) (*http://www.regulations.gov/#!docketDetail;D=FDA-2004-P-0210*). The CSPI petition claimed that trends of increasing sizes of snack foods and beverages make the current Nutrition Facts label on some products misleading for the average consumer. The CSPI petition discussed three groups of products: Soft drinks, snack food products, and baked goods. The CSPI petition claimed that larger package sizes for snack food products and soft drinks have led to increased consumption of these items, which contributes to the obesity epidemic. The CSPI petition requested that we improve the nutrition labeling in three areas for foods and beverages. Specifically, the CSPI petition requested that we: (1) Amend the definition of a single-serving container by increasing the cutoff for single-serving containers to include 300 percent of the applicable RACC for soft drinks/beverages and muffins/pastries; (2) consider whether the cutoff level for the single-serving labeling of other food categories should be raised; (3) require dual columns on the Nutrition Facts label on a per serving and per package basis for snack packages that contain at least 200 percent and up to and including 400 percent of the applicable RACC, if the snack package can be consumed by one person, but is often consumed by multiple people; (4) require snack packages that contain at least 200 percent and up to and including 400 percent of the applicable RACC to be labeled as a single serving if the package is usually consumed by one person; and (5) require disclosure on the principal display panel (PDP) of food labels for products that contain at least 200 percent and up to and including 400 percent of the applicable RACC of the number of servings in the package. We discuss issues raised in the first four requests from the CSPI petition in sections II.C.2.b and II.C.3.b. The fifth request for requiring disclosure on the PDP of food labels on the number of servings in the package for certain size packages is outside the scope of this rulemaking.

b. Petition for a New RACC for Fruitcake

We received a citizen petition (the fruitcake petition) on September 15, 2008, from certain fruitcake manufacturing companies (Docket No. FDA–2008–P–0511) (*http://www.regulations.gov/#!docketDetail;D=FDA-2008-P-0511*), requesting that we exercise administrative discretion to establish 43 g (~1½ oz) as the RACC for fruitcake rather than the current RACC of 125 g. The fruitcake petition provided labels, order forms, and other documents establishing that the fruitcake industry has been using 1½ oz as a serving size. The fruitcake petition did not provide any consumption data to establish a RACC. We will be discussing issues raised in this citizen petition in section II.D.3.b.

c. Petition for a New RACC for Yogurt

On June 2, 2011, the National Yogurt Association (NYA) submitted a citizen petition (Docket No. FDA–2011–P–0440) (the NYA petition) (*http://www.regulations.gov/#!docketDetail;D=FDA-2011-P-0440*), requesting that we change the existing RACC for yogurt from 225 g (roughly 8 oz) to 170 g (6 oz). Nutrient content claims and health claims for yogurt are based on the 8-oz RACC (§ 101.12(g)). According to the petition, over half of the yogurt containers on the market today are sold in 6-oz containers. However, manufacturers cannot make nutrient content claims and health claims for yogurt based on a 6-oz amount, because the 8-oz RACC must be used to determine if the criteria for the claims has been met (see § 101.12(g)). The NYA petition used current consumption data to justify their request for a smaller RACC. We discuss the issues in the NYA petition in section II.D.3.b.

d. Petition for a New RACC for Mint Wafers and Similar Candy Products

On February 17, 1996, we filed a petition submitted by the Nutrition Research Group for Andes Candies, Inc., (the Andes petition) (Docket No. FDA–1996–P–0309, formerly Docket No. 96P–0023) *http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=FDA-1996-p-0309;fp=true;ns=true*. The petition requests that we amend the RACC for Andes mint wafers and products that are similar to Andes mint wafers. Specifically, the Andes petition requested that we: (1) Change the RACC for Andes mint wafers and similar products from 40 g (the current RACC for ''All other candies'') to 15 g; and (2) amend the ''Sugars and Sweets'' product category for ''Hard candies, others'' to read ''Hard candies, mint wafers and others''.

The Andes petition provided data from a 1995 consumer study conducted by Andes to support a RACC of 15 g for

Andes mint wafers. The Andes petition also stated that the USDA national food consumption data available at the time (1995) also supported a RACC of 15 g for Andes mint wafers. These data included the 1987–1988 NFCS and 1989–1991 Continuing Survey of Food Intake by Individuals (CSFII).

e. Petition for a New RACC for Certain Candies Weighing 20 g or Less per Piece

On May 30, 1996, the Chocolate Manufacturers Association (CMA) and the National Confectioners Association (NCA), trade associations representing chocolate and confectionary companies, jointly submitted a citizen petition (the CMA/NCA petition) to FDA (Docket No. FDA–1996–P–0246, formerly Docket No. 96P–0179) *http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=FDA-1996-P-0246;fp=true;ns=true*. The CMA/NCA petition requested that we amend the ''Sugars and Sweets'' general category by establishing a new 25 g RACC for candies (other than hard candies or baking candies) weighing 20 g or less per piece.

The CMA/NCA petition pointed out that the current 40 g RACC for ''All other candies'' encompasses a large variety of candy products, ranging from very small pieces weighing only a few grams each, to king-size candy bars and novelty items that can weigh more than a pound. CMA/NCA submitted data from two consumer studies to support their request for a new 25 g RACC. The CMA/NCA petition concluded that a smaller RACC for chocolate and non-chocolate candies (other than hard candies or baking candies) weighing 20 g or less was warranted, and would result in labels that provide more useful nutrition information to consumers.

We discussed the Andes petition and the CMA/NCA petition in a proposed rule entitled ''Food Labeling; Serving Sizes; Reference Amounts for Candies'' on January 8, 1998 (63 FR 1078) (Docket Nos. FDA–1996–P–0309 and FDA–1996–P–0246 (formerly Docket Nos. 96P–0023 and 96P–0179)). Later, we announced the withdrawal of that proposed rule in the **Federal Register** on November 26, 2004 (69 FR 68831). Because we are updating, modifying, or establishing RACCs for all product categories in this proposed rule, we discuss the issues raised in the Andes petition and the CMA/NCA petition in this proposed rule. These issues are discussed in sections II.D.3.b and II.D.6., respectively.

f. Petition for a New Product Category and New RACC for Small Breath Mints Weighing 0.5 g or Less

We received a petition (the breath mints petition) dated April 20, 1994 (Docket No. FDA–1994–P–0314, formerly Docket No. 94P–0168) (*http://www.regulations.gov/#!documentDetail;D=FDA-1994-P-0314-0001*) from Ferrero USA, Inc. requesting that we amend the product category for ''Sugars and Sweets: Hard candies, breath mints'' to create a separate product category for small breath mints (weighing 0.5 g or less) having the same breath-freshening capacity as larger mints. The breath mints petition explained that small breath mints weigh about 0.4 g each, and therefore the current RACC of 2.0 g is unrealistic for this product category because it means the serving size would be 5 mints. The breath mints petition emphasized that because consumers typically eat one breath mint at a time, the serving size for small breath mints should be ''1 mint'' and that the RACC for this product category should be 0.5 g.

The breath mints petition contained study data collected from two telephone interviews with a randomly selected, nationally representative sample of consumers who acknowledged using breath mints during the past three months. The results of these studies, which included data on both small and large breath mint products, indicated that one breath mint was the amount customarily consumed per eating occasion by the majority of breath mint users. We also received two letters from breath mints manufacturers suggesting that breath mint products should have a ''one mint'' serving size (Refs. 12 and 13).

We discussed the breath mints petition in a proposed rule entitled ''Food Labeling; Serving Sizes: Reference Amount and Serving Size Declaration for Hard Candies, Breath Mints'' on December 30, 1997 (62 FR 67775) (the 1997 breath mints proposed rule) (Docket No. FDA–1994–P–0314, formerly Docket No. 94P–0168). This proposed rule also discussed changing the rounding rules for calories to allow the nutrition label on any product with less than 5 calories per serving to optionally declare the exact amount of calories in lieu of zero calories.

Because we are addressing issues related to the label serving size for breath mints, in conjunction with other serving size issues, in this proposed rule, we are withdrawing the 1997 breath mints proposed rule elsewhere in this issue of the **Federal Register**.

E. Technical Issues

Since the 1993 serving size final rule and the 1993 technical amendments were published, we have been alerted to several additional technical amendments that should be made. These technical amendments include: (1) Clarifying the rounding rules for products that have more than five servings when the number of servings fall exactly between two values; (2) clarifying options when the number of servings per container varies; (3) making minor corrections to the general and product category names; (4) making minor changes in the footnotes to the tables in § 101.12(b); (5) making minor changes to Table 2 in § 101.12(b); (6) making minor corrections and clarifications to the rules for reference amounts for products that require further preparation (e.g., mixes); and (7) clarifying the rules for reference amounts for products that consist of two or more separate foods that are packaged together and are intended to be eaten together (e.g., pancake and syrup). These amendments are discussed in section II.F.

II. The Proposed Rule

A. Legal Authority/Statutory Directive

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 at this time we have determined that amendments to those regulations are needed. We have analyzed consumption data for various food products, and have determined that many of the RACCs established in 1993 have changed enough to warrant amending the current RACCs. Additionally, both on our own initiative and in response to various requests, we have analyzed data for products that are not currently listed in the tables in § 101.12(b), and are proposing to establish additional RACCs. Thus, in accordance with section 403(q)(1)(A)(i) of the FD&C Act, we are proposing to amend the RACCs

in § 101.12(b) to reflect the current amounts customarily consumed for products that are already listed in § 101.12(b), as well as those not currently listed in § 101.12(b). Additionally, under the same authority we are proposing to amend related regulations in §§ 101.9 and 101.12 that set forth procedures for determining serving sizes for use on product labels from the reference amounts. Included among these proposed 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 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 proposing to amend § 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 preexisting columns listing the quantitative amounts and percent DVs for a serving of food that is less than the entire container. Section 2(b)(1)(A) of the NLEA provides authority for this proposed 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 is discussed further in section II.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 proposed 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 proposed amendments in this rule include 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)). 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 (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 deemed 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 proposed rule related to serving size labeling.

B. Need for This Regulation

Since we adopted the Nutrition Facts and Supplements Facts labels, there have been developments that have compelled us to re-evaluate 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 helping consumers maintain healthy dietary practices. Specifically, such developments include the availability of newer consumption data; research showing that the amount of food consumed by the American public has changed; and the availability of recent findings of consumer research on the use and understanding of the Nutrition Facts label. In light of these factors, we propose to amend the serving size regulations to provide consumers with information, including the serving size, in order to help them maintain healthy dietary practices. These factors are discussed in sections II.C.1 and II.D.1.

The proposed amendments are important because poor dietary practices have public health impacts (Refs. 14, 15, 16, 17, 18, and 19). Since 1993, there has been a shift in the population prevalence of being overweight or obese among the U.S. population. The U.S. Centers for Disease Control and Prevention (CDC) identifies as overweight an adult whose body-mass index, or BMI (defined as weight in kilograms divided by the height in meters squared), is between 25 and 29.9. CDC defines an obese adult as a person 20 years of age or older whose BMI is 30 or above (Ref. 16). CDC data indicate that 68 percent of the adult U.S. population is overweight or obese, including 34 percent who are considered obese (Ref. 14). The prevalence of obesity in the United States has increased dramatically in the past 30 years. In the 1976–1980 NHANES II data, 15 percent of participants were obese, while in the 2007–2008 NHANES data, 34 percent of people were obese (Refs. 14 and 15). The primary risk factors for overweight and obesity in the general population are overconsumption of calories (i.e., eating more calories than are needed to maintain body weight) and physical inactivity (i.e., getting an amount of exercise below the amount required to burn excess calories consumed over the amount needed to maintain body weight) (Ref. 7). For adults, being overweight or obese increases the risk for a number of chronic diseases, including coronary heart disease, type 2 diabetes, stroke, hypertension, arthritis, and certain types of cancer (Ref. 16). A BMI over 35 is associated with excess mortality, primarily from cardiovascular disease, diabetes, and certain types of cancer (Refs. 14, 17, and 19). Heart disease, cancer, and, stroke account for more than 50 percent of all deaths in the United States each year (Ref. 18). In 2005, 133 million Americans (almost one out of every two adults) had at least one chronic illness (Ref. 18).

In addition, portion sizes of foods served at home and in restaurants have increased. The package or portion sizes of foods purchased at supermarkets, stores, fast food restaurants, and chain restaurants were two to eight times larger than serving size standards set by Federal Agencies, including the USDA's Food Guide Pyramid and FDA's serving size standards, based on RACCs (Ref. 4). This change has been especially true for portion sizes of salty snacks, soft drinks, fruit drinks, and some fast foods (Ref. 6).

Studies have shown that increases in package size and portion size are related to higher calorie intake among individual consumers and overconsumption in American culture (Refs. 20, 21, 22, 23, and 24). In a study conducted by Rolls et al., participants were given afternoon snacks in prepackaged containers with varying portion sizes. They were given dinner later in the day to determine the effects of varying snack sizes on the subsequent meal. Study results showed that snack intake increased significantly as the package size increased. In most cases, participants did not significantly reduce

intake at dinner to compensate for the increased calorie intake from the snack, and overall combined calorie intake from the dinner and snack increased when subjects were given larger snack packages (Ref. 21). The primary risk factors for overweight and obesity in the general population are overconsumption of calories and physical inactivity (Ref. 7). Therefore, it is significant that increased package and portion size may contribute to increase consumption of total calories.

In consideration of all of the previously-mentioned factors, amendments to the serving size requirements are necessary to help consumers maintain healthy dietary practices. These amendments are described in sections II.C.2.b, II.C.3.b, II.D.2.c, II.D.3.b, and II.F. We invite comments on all aspects of this proposed rule, including the amendments described in these sections.

C. Single-Serving Containers and Dual-Column Labeling

FDA regulations require that a product that is packaged and sold individually and 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, except that, for products that have RACCs of 100 g or 100 mL or larger, manufacturers may decide whether a package that contains more than 150 percent, but less than 200 percent of the RACC, will be labeled as 1 or 2 servings (§ 101.9(b)(6)). In the 1991 serving size proposed rule, we proposed to set the upper limit of a single-serving container at ''less than 200 percent,'' in part, because products that contain 200 percent of the reference amount are, by definition, two servings. Thus, they are not single servings (56 FR 60394 at 60398). A reference amount is an amount customarily consumed (section 403(q)(1)(A)(i) of the FD&C Act). The RACCs we established are based primarily on nationally representative food consumption data and represent the amount of a food that a U.S. individual customarily consumes per eating occasion. Thus, if a product contains 200 percent or more of the applicable RACC, this amount would be twice as much as the customarily consumed amount per eating occasion.

Section 101.9 provides various provisions for types of voluntary dual-column labeling (e.g., § 101.9(b)(10)(i)) and one provision for mandatory dual-column labeling under certain circumstances (§ 101.9(b)(11)).

As explained in detail in this document, we are amending § 101.9(b) to change the criteria for when a food product must be labeled as a single serving, and to require the use of dual-column labeling that provides nutrition information per serving and per container, or per serving and per unit of food under certain circumstances.

1. Research Related to Single-Serving Containers and Dual-Column Labeling

a. Research on the Impact of Package and Portion Sizes on Consumption

Research has shown that package and portion sizes have a considerable impact on the amount of food consumed, and that the size of the unit of food or package can set a consumption norm for consumers (Refs. 25 and 26). In one study, moviegoers were given either medium or large containers of popcorn that were either fresh or stale (Ref. 25). Study results showed that moviegoers who were given fresh popcorn in larger containers ate 45.3 percent more popcorn than those given medium containers of fresh popcorn. Moviegoers who were given stale popcorn in large containers still ate 33.6 percent more popcorn than those given medium containers even though they reported that they disliked the popcorn (Ref. 25). In another study, subjects were given four different sizes of a deli sandwich, which were 4-inches, 6-inches, 8-inches and 12-inches. The results show that increasing the portion size of a food in a discrete unit, such as a sandwich had a significant effect on calorie intake (Ref. 26). These and other studies have demonstrated that the size of the package or unit may implicitly suggest what might be construed to be a ''normal,'' or ''appropriate,'' amount of food to consume (Refs. 20, 25, and 26). Using young adults enrolled at one university, another study found that participants experienced portion distortion (perceiving large portion sizes as appropriate amounts to eat at a single-eating occasion) and needed guidance in monitoring how much they ate (Ref. 27). Studies have also 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. 28).

b. Research on Consumer Use and Understanding of the Serving Size Labeling

Research also 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. A review article of studies on nutrition labels in the United States, Canada, and Northern Europe has found that although consumers could understand some information, they reported finding nutrition labeling confusing, especially the use of numerical information (Ref. 28). One study looked at participants of different socioeconomic backgrounds (Ref. 29). It found that only 32 percent of study participants could correctly calculate the amounts of carbohydrates in a 20 oz bottle of soda that had 2.5 servings in the bottle. Only 60 percent of participants could correctly calculate the amount of carbohydrates consumed if they ate half a bagel, when the serving size was a whole bagel (Ref. 29). Common errors found in the study were that participants: (1) Did not attempt to apply the serving size or servings per container information, or used it inappropriately; (2) were confused by complex information on the label; and (3) had calculation and other errors. Similar results were reported in the ''Calories Count'' report. Although some focus group participants knew how to correctly multiply by the number of servings to calculate nutrition information per package, others were confused or made mathematical mistakes (Ref. 2).

Other research conducted suggests that individuals might not make the distinction between serving size labeling and total package nutrition information, which could result in consumers considering the entire package as one serving despite the declaration of multiple (e.g., 2) servings per container on the Nutrition Facts label. For example, in one study, participants were interviewed to determine whether they could calculate the total calories in sample snack food packages that contained two to three servings (Ref. 30). Ninety percent of the subjects correctly identified the number of calories per individual serving, but only 37 percent were able to recognize the number of calories per package (Ref. 30). Some subjects tended to think of the multiple-serving package as one serving, and they underestimated and under-reported caloric intake from snack food sources (Ref. 30).

c. Research on Dual-Column Labeling

Other research has shown 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 (Ref. 31). In one study, participants were given a snack food product and either a single-column nutrition label or dual-column nutrition label (i.e., labeling

indicating the nutrition information per serving and per package). Participants were classified as either dieters or non-dieters based on self-reported dieting behavior. Study results found that a dual-column label reduces snack food consumption when compared to a single-column labeling for people who are not currently dieting. When the dual-column label was used, non-dieters in the study ate smaller portions that were closer to those portions consumed by dieters. The authors of this study speculated that a dual column label works as a contextual cue that raises awareness of the amount of food consumed in a package among certain consumers (Ref. 31).

We will be conducting consumer research throughout this rulemaking. The overall goal of the consumer research is to help enhance our understanding of whether and how much modifications to the label format may help consumers use the label. The research conducted thus far has examined the effects of modifications to the Nutrition Facts label on foods that could reasonably be consumed at a single-eating occasion, but were sometimes listed as having more than one serving per container, such as a grab bag of chips or a frozen meal. Participants were randomly assigned to one of ten label formats that could be classified into three groups: Listing two servings per container with a single column (''two-serving single-column labels''), listing two servings per container with a dual-column that listed the nutrients in both ''per serving'' and ''per container'' columns (''dual-column labels''), and declaring the entire package as one serving and listing all of the nutrients as a single serving (''single serving per container labels''). The 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, and compared participants' overall attitudes toward these labels. The main findings are that 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 two-serving single-column labels (such as the current label). Overall, participants reported more positive attitudes toward single-serving and dual-column labels in comparison to two- serving single-column formats (Ref. 32).

2. Single-Serving Containers

a. Comments on the ANPRM Regarding Single-Serving Containers

Amending the Definition for Single-Serving Containers

The ANPRM invited comment on whether we should begin rulemaking to require packages that can reasonably be consumed at one-eating occasion to provide the nutrition information for the entire package (70 FR 17010 at 17013).

Most comments indicated that we need to address the labeling of packages that appear to be single-serving packages, but are actually labeled as containing multiple servings, which they considered to be ''fraudulent'' and ''deceitful.'' Many comments stated that manufacturers should not be allowed to list multiple servings for items that an average person would consume at one-eating occasion. Examples of such items consumed at one-eating occasion that commenters thought to be misleading included 16 and 20 oz bottles of carbonated beverages, canned soup, snack size packages of potato chips, corn chips and pretzels, individual packs and cans of fruit juice, microwave popcorn, canned chili and ravioli, packages of shelled nuts, iced tea, frozen entrees and meals, energy drinks, 5-inch pizzas, dairy beverages, pre-packaged lunches, vending machine items, pre-packed breakfast cereals, cookies, and crackers. Many comments also objected to the use of fractional portions when declaring the numbers of servings for these products (i.e., 2.5 servings) and noted that we should require nutrition labeling for the entire package for products that could reasonably be consumed at one-eating occasion. One comment understood the listed serving sizes to be recommendations, rather than amounts customarily consumed, and stated that serving sizes such as a single sandwich divided into 2 servings, a single muffin divided into 3 servings, or a single bag of chips sold as a side to sandwiches divided into 2 servings were very confusing and unrealistic.

We agree, in part, with comments that opposed individually packaged foods that appeared to be single-serving containers, but which declared two or more servings on their package labels. We agree that these types of packaged foods can be confusing to consumers; however, we do not agree that all of these products should be labeled as a single serving. As discussed in detail below, these types of products should provide nutrition information for the whole package, as the only column of nutrition information for some products, or with dual-column labeling for other products, which would provide nutrition information per serving and per container or per unit, as applicable. As discussed in section II.C.1.a., scientific evidence has shown that some consumers may tend to experience a ''unit bias,'' and view certain sizes of intact units/packages of food as a marker of the appropriate amount of food to consume, and thus consumers should be provided with nutrition information for the amount of calories and nutrients that they might reasonably consume in an individual package or unit (Refs. 25, 26, 30, and 33).

Several comments noted that requiring larger products that could be eaten in a single serving to include nutrition information for the entire package could be problematic or confusing to consumers in that the labels may encourage overconsumption.

We disagree with comments suggesting that providing nutrition information for the entire package would be problematic or confusing to consumers on the grounds that the labels may encourage consumers to eat more. In an FDA-commissioned study (Ref. 32), participants who viewed nutrition information for a food labeled as a single serving container tended to rate the products as less healthful on average than participants who viewed nutrition information for the same food declared as a two-serving product. As noted in a recent literature review (Ref. 34), people often expect that they can eat more of foods that they perceive as healthful. Research has shown that when smaller serving sizes were used to present nutrition information, participants were led to believe that they would experience less guilt after consuming the entire package and reported that they would be more likely to purchase these products than when nutrition information for the same products was declared using a larger serving size (Ref. 34). In light of the findings from FDA's research, which suggest that providing nutrition information for an entire package of a food that would be consumed in a single eating occasion could result in more discerning product judgments, and the conclusions by Chandon and Wansink (Ref. 34), the data to date suggest that providing nutrition information for the entire package would provide consumers with more accurate information about the nutritional significance of foods that are likely to be consumed in a single eating occasion. Therefore, FDA disagrees that providing nutrition information for the entire package would be problematic or

confusing to consumers or encourage overconsumption.

Finally, one comment indicated that the current nutrition labeling format and the criteria to define a single-serving container should be maintained because this would allow manufacturers flexibility to respond to their markets.

We disagree with the comment that states that the current criteria used to define a single-serving container should be maintained because it adds more ''flexibility to respond to their markets.'' The comment did not explain what it meant by ''flexibility to respond to their markets'' or why changes to the criteria used to define a single-serving container would not provide such flexibility. As is discussed in detail in the following section, the current criteria for the labeling of certain products as single-serving containers in § 101.9(b)(6) are not consistent with the current consumption data.

Criteria for Determining When a Product Is a Single-Serving Container

The ANPRM invited comment on the criteria we should use to determine which multi-serving products would require nutrition information for the entire package (70 FR 17010 at 17013). We also asked whether the criteria should be based on the total amount in the container, the types of food, or something else, and whether the current criteria to define single-serving containers should be changed (70 FR 17010 at 17013).

Most comments stated that single-serving labeling should be used even if a serving size is 200 percent or more of the applicable RACC when evidence indicates the product rarely is eaten by more than one person or at more than one time. Several other comments pointed out that factors such as whether a product is ready to eat, how the product is packaged (e.g., packaged in a re-sealable container), and how the food is presented by the media are relevant to determining whether a package is truly a single serving. Another comment stated that single-wrapped items, such as muffins or pastries, where the item is not divided should not be labeled as multiple servings. Several comments stated that foods containing one to three servings or less, regardless of the food, should list the nutrient information for the entire package (alone or with another column listing the nutrient information per serving). Another comment stated that sodas, chips, and candy bars should be labeled as single-serving containers if a package contained three servings under the current labeling requirements, and in instances when the package contains more than three servings, the product should be labeled as family sized.

One comment indicated that products containing and including 3.5 servings under the current labeling requirements should be labeled as a single-serving container. Another comment recommended that products containing two to four servings per container be labeled as a single-serving container for products that potentially could be consumed at a single-eating occasion. A comment also stated that if the food contained fewer than five servings, it should also have nutrition information provided per package. Lastly, a comment noted that allowing anything less than 200 percent of the RACC to constitute one serving was too high of a cutoff, which could cause confusion about the amount of a serving size and potentially encouraging overeating. The comment suggested that the cutoff for a single-serving container should be lowered to between 75 to 150 percent of the applicable RACC.

We do not agree that single-wrapped items such as muffins and pastries, which are not divided for consumption, should always be labeled as single-serving containers. As explained previously in this document, products that contain 200 percent or more of the RACC by definition contain more than one serving, because they contain at least two times the amount that is customarily consumed.

We also disagree with the comments that suggested the criteria for determining a single-serving container should be 200 percent or more of the RACC if the product is rarely eaten by more than one person, comments that suggested that the criteria should be 300 percent or less of the RACC, and with comments that suggested that the criteria should be 350 percent or less of the RACC. Products that contain 200, 300, or 350 percent of the RACC, by definition, contain 2, 3, or 3.5 servings, respectively, and thus are not single-serving containers. We also disagree that, in order to avoid encouraging overeating, the cutoff for a single-serving container should be lowered to between 75 to 150 percent of the RACC. Prior research has demonstrated that using smaller serving sizes to declare nutrition information may lead consumers to form more positive impressions of the nutritional attributes of foods than are warranted (Refs. 32 and 35). Therefore, we believe that lowering the cutoff for a single-serving container could increase the likelihood that the product would be perceived more positively, which in turn may encourage overeating. Further, as noted previously in section II.C.1.b., research shows that giving consumers nutrition information for the entire package will help them to more easily comprehend the nutrient amounts in the food.

b. Proposed Amendments for Single-Serving Containers

We are proposing to revise, in part, the definition of a single-serving container so that a product that is packaged and sold individually and contains less than 200 percent of the applicable RACC must be considered a single-serving container, and the entire content of the product must be labeled as one serving (proposed § 101.9(b)(6)) regardless of the size of the RACC of the product. Currently the definition of a single-serving container is a product that is packaged and sold individually and that contains less than 200 percent of the RACC. 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). Manufacturers of these products may decide whether a package that contains more than 150 but less than 200 percent of the applicable RACC can be labeled as having one or two servings. See § 101.9(b)(6). We provided this qualification for products with large RACCs based in part on comments to the 1991 serving size proposed rule.

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, at that time, 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 reference amounts of 100 g (or mL) or larger, 150 percent is a more reasonable cutoff for a single-serving container. As a result of this, we revised § 101.9(b)(6) to allow manufacturers to choose whether to declare 1 or 2 servings in packages that contain more

than 150 percent but less than 200 percent of the reference amount if the food in the package has a reference amount of 100 g (or mL) or larger.

For this 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 (i.e., those products with RACCs of at least 100 g or 100 mL) and products that have RACCs that are less than 100 g (or mL), using combined consumption data from the NHANES 2003–2008 surveys (Ref. 36). 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 and is expressed as the percent of the median consumption amount (Ref. 36). The result shows that the correlation coefficient is 0.18, 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'' or not. 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, the exemption from the requirement to label a product with a large RACC, and containing between 150 percent and 200 percent of the applicable RACC, as a single-serving container is no longer warranted. Additionally, 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. As discussed in section II.C.1., research shows that consumers have trouble accurately calculating the nutrient amounts in the entire package of a food that is labeled as containing multiple servings, and research also shows that package size tends to have a considerable impact on the amount of food consumed. Therefore, 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 amount of food that they are consuming.

We are not proposing to change the current cutoff of less than 200 percent of the applicable RACC as the criterion for labeling a product as a single-serving container. Additionally, we are not proposing to increase the cutoff of less than 200 percent of the applicable RACC because, by definition, a product that contains 200 percent or more of the RACC means that it contains at least twice as much as the RACC and it is not a ''single'' serving container. Under section 403(q)(1)(A)(i) of the FD&C Act, a serving size is an 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. Therefore, proposed § 101.9(b)(6) would remove the provision that products packaged and sold individually and containing 200 percent or more of the applicable RACC may be labeled as a single serving if the entire contents of the container can reasonably be consumed at a single-eating occasion.

For consistency with the proposed changes to the definition of a single-serving container, we propose to remove § 101.9(b)(2)(i)(E), which provides that if a discrete unit of food contains more than 150 percent but less than 200 percent of the RACC, the manufacturer may decide whether to declare the individual unit as 1 or 2 servings, for units that have large RACCs of 100 g (or 100 ml) or larger and are individual units within a multi-serving container. Also consistent with the changes in proposed § 101.9(b)(6), we are proposing to remove the text in current § 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 II.C.3.b). Finally, we also propose to redesignate § 101.9(b)(2)(i)(F) as § 101.9(b)(2)(i)(E), redesignate § 101.9(b)(2)(i)(G) as § 101.9(b)(2)(i)(F), redesignate § 101.9(b)(2)(i)(H) as § 101.9(b)(2)(i)(G), and redesignate § 101.9(b)(2)(i)(I) as § 101.9(b)(2)(i)(H), because the proposed rule would remove current § 101.9(b)(2)(i)(E).

3. Dual-Column Labeling—Mandatory Listing of a Second Column of Nutrient Values on the Nutrition Facts Label Based on the Entire Container or Unit

a. Comments on the ANPRM Regarding Dual-Column Labeling

Dual-Column Labeling Requirements

The ANPRM invited comment on whether to require certain products to include an additional column within the Nutrition Facts label to list the quantitative amounts and percent DVs for the entire package, as well as the required columns listing the quantitative amounts and percent DVs for a serving that is less than the entire package (i.e., the serving size derived from the RACC) (70 FR 17010–17013).

Some comments supported the use of dual-column labeling. One comment suggested dual-column labeling for products that may be consumed in their entirety at a single occasion, but often are shared or eaten over time. Several comments requested that we not require dual-column labeling on the packaging of all food products. These comments stated that any discussion of disclosing information per package should address only packages that potentially could be consumed by one person at a single-eating occasion or possibly shared between one or more persons. Other comments suggested that we provide dual-column labeling on all packages with multiple servings such as a family sized package of frozen lasagna.

We agree with comments supporting a requirement for the use of an additional column of nutrition labeling (i.e., dual-column labeling) under certain conditions. As discussed in section II.C.1.c., research suggests that dual-column labeling helps consumers understand what the nutrient amounts are in an entire container of food. We also agree that dual-column labeling should be used for products that may be eaten by one individual in one-eating occasion or over several-eating occasions, but may also be eaten by multiple individuals. Information on the nutrient amounts in an entire container of food would not be as relevant to consumers if the food could not reasonably be consumed by one individual in a single-eating occasion. For this reason, we agree that it is unreasonable to require dual-column labeling on the containers of all food products. As discussed in this section, data show that products that contain more than 400 percent of the RACC are less likely to be consumed in one-eating occasion when compared to products that contain 400 percent or less of the RACC (Ref. 37). For this reason, we do not believe it is appropriate to require a second column of nutrient values on containers that contain more than 400 percent of the applicable RACC. Additionally, the proposed rule would not require dual-column labeling for bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils); bulk products traditionally used for multi-purposes (e.g., eggs, butter, margarine); and

multipurpose baking mixes, because labeling these products with nutrition information based on the entire container would not be consistent with how these products are typically consumed.

We also do not agree with the comment that stated that dual-column labeling should be required for all multi-serving products, such as a family-sized package of lasagna. Products that contain more than 400 percent of the RACC are less likely to be consumed in one-eating occasion compared to products that contain 400 percent or less of the RACC (Ref. 37).

Some comments opposed mandatory dual-column labeling. A few comments opposed dual-column labeling noting that it would require changes that could cost a significant amount of money for companies and would use up valuable package space that is often used for other types of nutrition education messages. These comments noted that dual-column labels would be difficult for products with small label space. Some comments suggested that dual-column labeling be voluntary and not mandatory.

We agree that it may be difficult to fit an extra column of nutrition information on the labels of some products. However, many food packages, such as grab-size bags of chips, cookies, crackers, and frozen entrees that would be affected by the proposed dual-column labeling requirements provide enough space to accommodate a second column of nutrition information based on the entire container. We address the concern about providing dual-column labels for small products with a limited amount of space on the Nutrition Facts label in section II.C.3.b.

We also agree that a dual-column labeling requirement would have some costs for industry. The costs of the proposed dual-column labeling requirement are addressed in section IV.

Dual-Column Labeling and Consumer Understanding

The ANPRM invited comment on how listing the nutrient amount per serving size and per package side-by-side in separate columns would affect consumers' ability to understand the Nutrition Facts label (70 FR 17010–17013).

A few comments that objected to the use of dual-column labeling stated that the second column of values would be confusing to consumers or provide too much information, and would thus contribute to label clutter. Several comments noted that dual-column labeling may confuse the consumer in that it could imply to consumers that larger serving sizes were a recommended amount to consume and would have the opposite effect from what was intended and result in overconsumption. These comments also stated that consumers may not need, want, or understand why this information is on the label and how this quantity differs from a typical serving size. One comment noted that a problem with dual-column labeling was that consumers were unlikely to be interested in information provided in the second set of nutrition values and that the nutrition label format would become more complicated, potentially making the Nutrition Facts labels less friendly and manageable. None of these comments, however, provided data or information to support the possible consumer reactions identified.

We are not convinced that dual-column labeling may be confusing to consumers and that dual-column labeling would imply that consumers should eat more of an item. In fact, as discussed in section II.C.1.c., research findings from a study suggest that dual-column labeling would lead consumers who are not dieting to reduce rather than increase the amount of food they consume as suggested by comments (Ref. 31). We also conducted a study (Ref. 32) to help enhance our understanding of whether and what types of modifications to the label format may help consumers use the label. The main finding was that single serving per container labels and dual-column labels resulted in more participants correctly identifying the number of calories per container and the number of other nutrients per container and per serving compared to two-serving single-column labels (such as the current label) (Ref. 32).

One comment suggested that an appropriate and informative approach may be to have products that can be consumed in one-eating occasion provide both ''Servings Per Package'' and ''Calories Per Package'' near the top of the Nutrition Facts label. Finally, multiple comments noted that modifying the Nutrition Facts label would require consumer re-education on how to read an amended Nutrition Facts label.

We tested a format similar to the one suggested in the comment, in which ''Servings Per Package'' and ''Calories Per Serving'' were in close proximity, in our consumer study (Ref. 32). The test format included a listing of ''Calories in 1 cup serving'' followed by the declaration of servings per container (i.e., ''2 Servings per container'') near the top of the Nutrition Facts label (Label 4). Results from this study showed that dual-column labels were read with somewhat better accuracy when compared against labels that were similar to the one suggested in the comment. Based on these results, we do not agree with the comment.

We agree with the comment that modifying the Nutrition Facts label would require some re-education on how to read the Nutrition Facts label. We consider it important to provide consumers with education and outreach on nutrition labeling. We will consider appropriate education methods after the publication of this proposed rule.

Criteria for Determining Dual-Column Labeling

The ANPRM did not address the criteria to be used to determine what types of products should require dual-column labeling. However, some comments provided criteria for the use of dual-column labeling on Nutrition Facts labels based on the quantity of food in the container. One comment suggested that dual-column labeling on the Nutrition Facts label could be required for products that contained 200 to 300 percent of the RACC, unless the Nutrition Facts label for the product provided a single column for the entire packaged amount. The comment further suggested that for products with RACCs of 100 g or 100 mL or greater, and that contain more than 150 percent but less than 200 percent of the RACC, dual-column labeling could be optional, similar to the existing requirement for the Nutrition Facts label declaration for single-serving containers. Finally, the comment suggested that dual-column labeling should not be required for products that: (1) Contain up to 150 percent of the RACC or (2) contained 5 calories or less per RACC and were not fortified. Another comment suggested that products with 2, 3, or 4 servings per container that are likely to be consumed at a single-eating occasion be required to add an additional column with a disclosure for calories per container at the top of Nutrition Facts label, just below the servings per container. Other comments requested that information based on the entire package be listed for products with up to five servings and that this information be provided in a second column of the label.

In consideration of an upper limit for dual-column labeling, we looked at food consumption data from the NHANES 2003–2008 surveys. Dual-column labeling can, in part, provide information for products that may be consumed by one person in a single-eating occasion, but are oftentimes consumed by more than one person or

in more than one-eating occasion. To determine an upper limit for these products, we looked at NHANES 2003–2008 consumption data (Ref. 37). 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. Thus, the data suggest that 90 percent of the reported consumption amount is 400 percent of the RACC or less for almost all product categories, meaning that dual-column labeling for products with 400 percent or less of the RACC would capture the most frequent consumption habits for all product categories. Conversely, the data show that products that contain more than 400 percent of the RACC are less likely to be consumed in one-eating occasion compared to products that contain 400 percent or less of the RACC. An upper limit of 400 percent of the RACC for dual-column labeling would be consistent with the upper limit suggested in the CSPI citizen petition, which requested that we consider dual-column labeling for snack packages containing between 200 percent and up to and including 400 percent of the RACC.

Given the consumption data, we do not agree with the comments that suggested thresholds for requiring dual-column labeling for products that contain 200 to 300 percent of the RACC or the comments that suggested that dual-column labeling be provided for up to five servings. As noted in the preceding paragraph, the data suggest that 90 percent of the reported consumption amount is 400 percent or less of the RACC for almost all product categories. Therefore, based on the consumption data, 300 percent of the RACC appears to be too low of a cutoff level for dual-column labeling and 500 percent is too high.

We disagree with the comment that suggested that for products with RACCs of 100 g or 100 mL or greater, and that contain more than 150 percent but less than 200 percent of the RACC, dual-column labeling could be optional, similar to the existing requirement for the Nutrition Facts label declaration for single-serving containers. As noted previously in section II.C.2.b, current consumption data indicate that there is no difference in intake of large RACC products containing 100 g or 100 mL or greater and smaller RACC products. Therefore, there is no need to make a distinction for large RACC products. Additionally, we are proposing to require that all products that contain less than 200 percent of the RACC be labeled as a single serving. Therefore, a proposal for dual-column labeling for these packages is unnecessary, because the products would already contain nutrition information based on the amounts in the entire container under the proposed revisions to the single-serving requirements.

We agree with the comment that suggested that dual-column labeling should not be required for products that contain up to 150 percent of the RACC. As noted previously in section II.C.2.b, we are proposing that all products packaged in containers with less than 200 percent of the RACC must be labeled as a single serving and have a Nutrition Facts label per container only. However, we disagree with the second part of the comment that suggested that dual-column labeling should not be required for products that contained 5 calories or less per RACC and were not fortified. If we were to adopt this provision, then this would allow for products, such as diet soft drinks, to be exempt from dual-column labeling. We believe that, for consistency purposes, dual-column labeling should apply to these products as well. This will allow consumers to view the same type of label and make an easy comparison when looking at different soft drinks.

b. Proposed Amendments for Dual-Column Labeling

We have carefully considered all available data, information, and comments for and against a second column of nutrient values based on the entire container and have concluded that mandatory labeling of a second column of nutrient values based on the entire container for containers that contain 200 percent and up to and including 400 percent of the applicable RACC is warranted. This 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. We base our conclusion, in part, on results of a consumer study we conducted that suggested that dual-column labels resulted in more participants correctly identifying the number of calories per container and the number of other nutrients per container and per serving compared to two-serving single-column labels (such as the current label) (Ref. 32). In addition, we are basing our conclusion, in part, on another study that suggested that dual-column labeling would lead consumers who are not dieting to reduce rather than increase the amount of food they consume (Ref. 31). This additional awareness is important in light of studies that indicate that package sizes influence the amount consumers consume (Refs. 21 and 25). We are proposing the cutoff of 400 percent for dual-column labeling based on our analysis of the intake distribution per eating occasion for all products. Based on this analysis, we concluded that for each product the ratio of the intake at the 90th percentile level to the RACC was 400 percent or less. As such, dual-column labeling for products 400 percent or less of the RACC would capture the most frequent consumption habits for all product categories. We propose a threshold of 200 percent of the applicable RACC to trigger the requirement for dual-column labeling, because under the proposed requirements discussed in section II.C.2.b., all products containing less than 200 percent of the RACC would be labeled as a single-serving container (proposed § 101.9(b)(6)). Therefore, products containing less than 200 percent of the RACC will already contain nutrient information based on the contents of the entire container.

Consequently, we are proposing to add a new § 101.9(b)(12) which would 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. For example, under the proposed amendment, a manufacturer would have to use dual-column labeling on a bag of chips that contained 3 oz (90 g) (about 300 percent of the RACC). A major advantage of the proposed approach of dual-column labeling is that it will not require math to determine nutrition information for consumers who consume the entire container in a single-eating occasion and will continue to provide nutrient information per RACC for consumers who do not consume the entire container in a single-eating occasion, and for consumers who share the product. Thus, easily understandable information will be provided for all types of consumers of these products. For an example of a dual-column label as described in this section, see the proposed codified of the ''Food Labeling; Revision of the Nutrition and Supplement Facts Labels'' proposed rule published elsewhere in this issue of the **Federal Register**.

In addition to proposing dual-column labeling per serving and per container

(or unit, as applicable) for all nutrition information on the label, we are considering two additional options that would require nutrition information per serving and per container for only certain declarations but not all label declarations for containers of food or units of food, as applicable, containing at least 200 percent and up to and including 400 percent of the applicable RACC. The first option is for a label that includes calorie information per serving and per container (or unit, as applicable) following the serving size information in the Nutrition Facts label. With this option, the remaining nutrition information would be listed on a per serving basis only and in a single column below the calorie information per serving and per container. The second option is to provide nutrition information per serving and per container (or unit, as applicable) for calories, saturated fat and sodium following the serving size information in the Nutrition Facts label and the remaining nutrition information would be listed on a per serving basis in a single column below the dual column provided for calories, saturated fat and sodium declarations. These options may specifically highlight the calorie content alone, and the calorie content, saturated fat content, and sodium content, respectively, for both the serving size and the entire container of food (or unit, as applicable). These options would focus on a smaller number of nutrients presented per serving and per container of food (or unit, applicable) that the U.S. population should limit for those foods with at least 200 percent and up to and including 400 percent of the RACC. We question whether consumers would be more inclined to use dual column labeling for a smaller set of nutrients. We invite comment and data on dual column-labeling as proposed in this rule as well as the options presented for providing nutrition information per serving and per container (or unit, as applicable) for only certain declarations.

For consistency with proposed § 101.9(b)(12), the proposed rule would change § 101.9(b)(2)(i)(D). Section 101.9(b)(2)(i)(D), which applies to products in discrete units within a multi-serving container, provides that if a unit weighs 200 percent or more of the RACC, the manufacturer may declare the whole unit as the serving size if the whole unit can reasonably be consumed at a single-eating occasion. As noted previously, we are proposing to delete the current text in § 101.9(b)(2)(i)(D) and to replace it with text requiring that products that are discrete units within any size of a multi-serving container, and contain at least 200 percent and up to and including 400 percent of the applicable RACC (e.g., a container of six muffins where each muffin contains 200 percent of the RACC), have an additional column within the Nutrition Facts label that lists the quantitative amounts and percent DVs for each discrete unit, as well as the preexisting columns listing the quantitative amounts and percentage DVs for a serving that is not based on the discrete unit (i.e., the serving size derived from the RACC).

We are also proposing in § 101.9(b)(12)(i)(B) that the provisions for dual-column labeling would not be required for bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or bulk products traditionally used for multi-purposes (e.g., eggs, butter, margarine), and multipurpose baking mixes because labeling these products with nutrition information based on the entire container would not be consistent with how these products are typically consumed. Finally, due to limitations in labeling space, proposed § 101.9(b)(12)(i)(A) would state that 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) are exempt from dual-column labeling.

We are aware of several food products that require further preparation, and contain at least 200 and up to and including 400 percent of the applicable RACC, such as macaroni and cheese kits, pancake mixes, pasta products, and rice products. 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)). Most of these products voluntarily contain two columns of nutrition information on the ''as purchased'' and ''as prepared'' forms of the food. Therefore, we tentatively conclude 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, should be exempt from the dual-column labeling requirement under proposed § 101.9(b)(12)(i). For products requiring further preparation for consumption, it is helpful to consumers to include nutrition information based on the prepared form of the product in addition to the ''as purchased'' form of the product. If these products were required to use dual-column labeling with nutrition information for the serving size based on the RACC and nutrition information for the entire container, they would have to include at least three columns if they also voluntarily included one column of nutrition information representing servings per container for the prepared form of the food. Manufacturers could opt to not include the voluntary column for the prepared form of the food if we were to require dual-column labeling under proposed § 101.9(b)(12)(i) for their product. However, nutrition information based on the entire container of the unprepared food may be less meaningful to consumers than information on a serving of the prepared form of the food, because these types of products are meant to be consumed after further preparation. Thus, the proposed rule would exempt food products that require further preparation and also include voluntary labeling of ''as purchased'' and ''as prepared'' forms of the food under § 101.9(e) from the provisions of dual-column labeling (proposed § 101.9(b)(12)(i)(C)). Likewise, the proposed rule would exempt products that are commonly consumed in combination with other foods (e.g., cereal and skim milk) and that include another column with information regarding that combination as specified in § 101.9(e) and (h)(4) (proposed § 101.9(b)(12)(i)(C)). As is the case with foods that require further preparation, nutrition information based on the entire container of an uncombined food (for a food that is commonly combined with another food) may be less meaningful to consumers than information on a serving of the combined food, because these types of products are commonly consumed in combination with another food. For consistency, FDA is also proposing that the exemptions under §§ 101.9(b)(12)(i)(A), (B), and (C) apply to the dual-column labeling requirement under proposed § 101.9(b)(2)(i)(D) as well.

We invite comments on our tentative conclusion that products requiring further preparation and products that are commonly consumed in combination with other foods, and that voluntarily provide another column of nutrition information under § 101.9(e), should not be required to provide dual-column labeling under proposed § 101.9(b)(12)(i) or § 101.9(b)(2)(i)(D). Additionally, we invite comments regarding whether any other products that voluntarily include an additional column (or multiple columns) of nutrition information under our regulations (e.g., products for which

RDI's are established for two or more groups, as discussed under § 101.9(e)) should be exempt from the proposed dual-column labeling requirements under § 101.9(b)(12)(i) or § 101.9(b)(2)(i)(D).

Use of Nutrient Content Claims and Health Claims on Products With Dual-Column Labeling per Serving and per Container

RACCs are used to determine whether individual foods are eligible to bear nutrient content and health claims (§ 101.12(g)). If dual-column labeling is finalized as proposed, nutrition information will be presented on a per serving basis and on a per container or per unit basis, as applicable. To clarify that the level of the nutrient that is the subject of the claim is based on the RACC and not the amount in the entire container or unit of food, proposed § 101.9(b)(12)(ii) would require that the claim be followed by a statement that sets forth the basis on which the claim is made. The statement must express the amount of the nutrient in a serving for a nutrient content claim (e.g., ''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''). However, if the serving size declared on the product label differs from the RACC, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim must be followed by the criteria for the claim as required by § 101.12(g). We are also proposing that the statement that sets forth the basis on which the claim is made would not be required for products when the nutrient that is the subject of the claim meets the criteria based on the entire container amount or unit amount, as applicable.

D. Reference Amounts Customarily Consumed

The RACCs in the tables listed in § 101.12(b) are arranged by categories. The broadest category is the ''general category.'' There are 21 general categories, which separate the food products into broad groups, with similar types of products placed together. Examples of general categories are ''Beverages'' and ''Desserts.'' In each general category, there are product categories. As noted previously in this document, currently there are RACCs for 129 product categories for people 4 years of age or older in Table 2 of § 101.12(b) and 11 product categories for infants and children 1 through 3 years of age in Table 1 of § 101.12(b), for a total of 140 product categories. A product category is a group of products with similar dietary usage. The RACCs are assigned by product categories. In some cases, in the tables listed in § 101.12(b), examples of the types of products in the product category are listed.

The current RACCs for the 140 product categories are derived primarily from food consumption data from the 1977–1978 (*http://www.ars.usda.gov/Services/docs.htm?docid=16184*) and 1987–1988 (*http://www.ars.usda.gov/Services/docs.htm?docid=16185*) NFCS conducted by the USDA. In light of newer consumption data, newer food products in the market place, comments received on the ANPRM, several written requests (Refs. 8, 9, and 10) and four citizen petitions (the fruitcake petition, the NYA petition, the CMA/NCA petition, and the Andes petition), we are proposing to update, modify or establish RACCs. Updating RACCs refers to proposed amendments to RACCs for products that are currently listed in the tables in § 101.12(b), and for which the NHANES 2003–2008 consumption data showed an increase or decrease in consumption by at least 25 percent. Modifying RACCs refers to changes to existing 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 by at least 25 percent. Establishing RACCs refers to the addition of products (and assigning RACCs for such products) that are not already listed in the tables in § 101.12(b). In Section II.D.2. we are proposing to update the RACCs for selected categories for products that are already in the tables in § 101.12(b). In section II.D.3., we are proposing to modify or establish new RACCs based, in part, on requests to establish new RACCs for products that are not in the tables in § 101.12(b), modify the RACCs for selected products that are already in the tables in § 101.12(b), or add products to an existing general category or product category in the tables in § 101.12(b) (Refs. 8, 9, and 10). In section II.D.3., we are also proposing to modify some product categories on our own initiative. We invite comment on whether the RACCs and labeled serving size for certain products identified as products of concern in comments to the ANPRM should be updated. We also invite comment on whether we should propose changes to other product categories not amended by this proposed rule.

1. Research and Data Related to Updating, Modifying, and Establishing RACCs

We recognize that many consumers may consume substantially larger portions than the serving sizes presented on the Nutrition Facts label, and this could lead consumers to underestimate the number of calories and other nutrients consumed. The current RACCs used to determine serving sizes are based primarily on data obtained through 1977–78 and 1987–88 NFCS conducted by USDA. More recent empirical evidence suggests, however, that for many types of food the amount of food that Americans customarily consume has changed significantly since these data were collected. For instance, a review of nationwide food intake surveys from 1977–78, 1989, and 1996 concluded that portion sizes for numerous types of foods grew substantially between 1977 and 1996 (Ref. 6). Another review of data likewise concluded that portion sizes have increased substantially since the current RACCs were established (Ref. 5). Additionally, a study has noted the supersizing of portion sizes in America in recent years (Ref. 38).

Additionally, package sizes for many foods have increased, and the package size of a food product has been shown to have an impact on the amount of food that is consumed by a person. Package sizes in grocery stores, amounts served in restaurants, and dishware sizes at home could all influence how much people eat and their perceptions about portion sizes. In one study showing a link between larger portion sizes and increased calorie intake, participants were given all meals for two consecutive days each week for three weeks in a laboratory (Ref. 24). Each week the portion sizes of the meals varied from 100, 150, or 200 percent of the baseline amount. Results showed that a 50 percent increase in portion size led to a 16 percent increase in calorie intake and a 100 percent increase in portion size led to a 26 percent increase in calorie intake (Ref. 24).

We recognize that increases in portion and/or package sizes may play a role in overeating because the growth in portion and package sizes have coincided with the surge of obesity rates in the United States (Refs. 5, 6, and 39). We also recognize that the serving size can provide a usable reference point for evaluating the nutritional content of a food and is a critical tool to those trying to achieve or maintain a healthy lifestyle and/or body weight. The serving size can also help consumers select among food products based upon

calories and other nutrients per serving. However, to be an appropriate reference point, the serving size must be based upon a meaningful quantity of food, which is what the RACCs provide.

We have analyzed current data and determined that, for some product categories listed in the tables in § 101.12(b), the RACCs have changed. Additionally, we recognize 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 have led us to propose the amendments to the RACCs below. The proposed amendments would help convey clear and accurate information on serving sizes and the related nutritional profile of foods, which is important for consumers to be able to make choices that support a more healthful diet. Section II.D.2.c. discusses our proposals for updating existing RACCs and section II.D.3.b discusses our proposals for modifying and establishing new RACCs.

2. Updating Existing RACCs

This section discusses public comments, methods used for updating existing RACCs, and the changes that we are proposing to update existing RACCs.

a. Comments on the ANPRM Regarding Updating the Existing RACCs

Selection of Food Consumption Data Sources and Criteria for Changing the RACCs Established in 1993

The ANPRM invited comment on how recent food consumption data, such as data from the 1999–2000 and 2001–2002 NHANES, should factor into the determination of which, if any, RACCs need to be updated and if there are other food consumption data sources that are available, or that could be provided for our consideration (70 FR 17010–17012). We also asked what criteria should be used as the basis for changing the RACCs, if the RACCs were revised.

Most comments supported the use of national food consumption data to establish serving sizes. One comment suggested that we consider the USDA/Agriculture Research Service Automated Multiple Pass Method validation study (AMPM) which provides an overall picture of health and nutrition as a consumption survey tool. Some comments opposed the use of any data other than food consumption data, arguing that they do not fulfill the FD&C Act's requirement that the serving sizes reflect amounts customarily consumed.

Some comments advised us against using current data to establish updated RACCs. These comments indicated that basing serving sizes on current consumption data was unsound from a policy perspective in that it could suggest to consumers they could or should eat larger amounts, which contradict current efforts to curb obesity as well as federal dietary recommendations. Some comments reasoned that food consumption data have many limitations, and therefore it is not possible to derive accurate estimates of the customarily consumed amounts from such data. Several comments indicated that nutrition survey data are not appropriate and there is no justification to base serving size on food consumption data because these data have known inaccuracies.

Regarding the comments on how food consumption data should factor into updating the RACCs, we note that none of the comments opposing the use of consumption data to establish RACCs provided any alternative sources of data to use. Section 403(q)(1)(A)(i) of the FD&C Act states that a serving size is the amount customarily consumed, making food consumption data the best source for determining serving sizes. In addition to the variability among individuals, we are aware of the limitations of the available food consumption databases. However, these databases are still the best sources of food consumption data collected under actual conditions of use available to us. Thus, we conclude that the use of food consumption data as the primary source for the customarily consumed amounts of food for nutrition labeling purposes is appropriate.

Regarding the comment suggesting that we consider the USDA/Agriculture Research Service Automated Multiple Pass Method validation study, this study as well as the food consumption data are used as part of our methodology to determine which RACCs to update. It is discussed further in section II.D.2.b.

With respect to the comment that suggested that basing serving sizes on current consumption data was unsound and could suggest to consumers they could or should eat larger amounts, our authority states that RACCs must be based on the amount customarily consumed. However, we understand that educational outreach may be needed in the future to clarify this information to consumers.

With respect to the criteria that should be used as the basis for change if the RACCs are revised, one comment indicated that applying percentages broadly across all product categories would not be fair to manufacturers of some product categories. For example, a 20 percent increase in intake of cereal with a 15 g RACC would equal a 3 g increase versus a 20 percent increase in the serving of a 55 g RACC cereal that would equal an 11 g increase. The comment suggested that we consider changes in weight or volume when updating RACCs.

We agree with the comment that applying percentages broadly across product categories would not be fair to some product categories. We are not proposing to update all RACCs using a percentage point, but rather propose to determine which RACCs should be updated by looking primarily at whether the amount consumed for each product in a product category increased or decreased by at least 25 percent compared to the RACCs established in 1993. Other factors as described below were also considered. When looking at the products in product categories, we are proposing that the unit of measurement for each category be taken into account.

The Impact of Updates to the RACCs on the Use of Nutrient Content Claims and Health Claims

Several comments stated that changes in serving sizes could have an unforeseen consequence of jeopardizing and negating the use of many nutrient content claims, such as ''low fat'' or ''reduced fat'' claims, and health claims on the product label. Some comments noted that some foods that typically would not be considered a ''good source'' of a particular nutrient might qualify if RACCs were to increase.

In response to comments regarding the impact of increasing serving sizes on nutrient content and health claims, we agree that changing the RACCs may have an impact on the health and nutrient content claims that can be made on certain products. However, such changes may be appropriate in light of the changes in the amounts of food being customarily consumed. For example, a product might qualify to bear a ''low fat'' nutrient content claim currently, but is actually being customarily consumed in amounts that contain more fat than would qualify for such a claim. Additionally, products that are not currently eligible for ''good source'' or ''excellent source'' claims may become eligible if the RACCs are increased. These products should be able to bear such claims if the consumption amount has increased enough to qualify the food for the claim.

Consumer Interpretation of ''Serving Size'' and Consumer Perception of Increased Serving Sizes

The ANPRM invited comment on whether consumers would think that an increase in serving size on food labels means that more of the food should be eaten and what additional education efforts should be provided to consumers to avoid such a conclusion. We also sought comment on whether we should reconsider the definition of ''serving'' and ''serving size'' or how we interpret ''customarily consumed.''

Many comments urged us to harmonize label serving sizes and RACCs with recommended dietary guidance and the Food Guide Pyramid. The comments indicated that an increase in serving sizes might suggest to consumers that they should eat larger portions. One comment indicated that if the serving size was increased to accommodate current consumption levels, consumers might choose to consume 125 percent of a new serving size which would result in increased consumption and is opposite of the intended effect. Some comments indicated that further science-based research is needed to obtain consumers' perceptions and reaction to serving sizes.

In response to the question concerning reconsidering the definition of serving size, two comments indicated that the terms ''serving'' and ''serving size'' may be confusing to consumers, because they are the same terms used in dietary guidance, such as the USDA Food Guide and the Dietary Guidelines for Americans. Other comments indicated that we should take into account dietary guidance recommendations when defining ''serving'' and ''serving size,'' or how we interpret ''customarily consumed.'' One comment suggested that ''FDA consider testing terms such as 'suggested serving size,' 'reasonable serving size,' or 'sensible serving size' to evaluate consumer usefulness.''

With regard to the comments that RACCs and serving sizes should be based on what people should eat rather than what they usually eat, we acknowledge that there may be benefits to have serving sizes on product labels that are consistent with the serving sizes in the dietary guidance documents published by Federal Government Agencies. However, the FD&C Act specifically defines serving size as an ''amount customarily consumed,'' rather than a recommended amount people should eat. In addition, dietary guidance documents published by Federal Government Agencies usually list approximate amounts of food for the purpose of providing ''general'' guidance as to what quantity of each food group a person should consume to maintain good health. Therefore, the amount that represents a serving is often not well defined. For example, dietary guidance documents define a serving of bread as 1 slice of bread. However, the weight of a slice of bread varies and would not be able to be converted into a reference amount without a specific gram weight. Another example is that the 2010 Dietary Guidelines for Americans recommended total cups to consume per day of fruits and vegetables, but does not list specific amounts of particular types of fruits and vegetables to be consumed per eating occasion (Ref. 7). In addition, not all foods are represented in the dietary guidelines while all foods would need to be represented in the serving size RACCs.

With respect to the comments that indicated that consumers might think that an increase in serving sizes on the food label suggest that they should eat larger portions, we agree that some consumers may misconstrue the meaning of the serving size. We recognize that research has shown that over half of consumers generally misunderstood the meaning of serving size on the food label to be a recommended amount (Ref. 40). Given this confusion among consumers, we will consider education efforts to help increase consumer understanding of the term serving size. However, we also note that some consumer comments on the ANPRM overwhelmingly indicated that current serving sizes in use are confusing and can be misleading. For example, some indicated that the RACCs and serving sizes currently in use (e.g., 2 servings on a 16 fl oz can of soft drink, or an 8 oz pot pie) are confusing because they do not reflect the amount of food that is currently customarily consumed. Providing the nutrition composition of the food based on current consumption amounts informs consumers of the amount of nutrients they are likely to ingest from a particular food.

In response to the comment suggesting that we consider testing terms such as ''suggested serving size,'' ''reasonable serving size,'' or ''sensible serving size'' to evaluate consumer usefulness, as previously explained, under section 403(q)(1)(A)(i) of the FD&C Act, serving size is based on the amount of food people customarily consume and is not a suggested or recommended amount of food to eat. The terms suggested by the comment are not an accurate indication of the value that the serving size represents.

b. Methods Used to Update the Existing RACCs

Food Consumption Database

To update existing RACCs that reflect the amounts of food products customarily consumed, we analyzed food consumption data from the NHANES 2003–2008 surveys to assess the amount of food reported consumed per eating occasion. The NHANES collects nutrition and health related measures among the civilian non-institutionalized U.S. population. The NHANES oversamples African Americans, Mexican Americans, low-income whites, adolescents 12 to 19 years of age, and persons 60 years of age and older. The dietary interview component of NHANES, called ''What We Eat in America'' (WWEIA), is conducted as a partnership between USDA and the U.S. Department of Health and Human Services (DHHS) (Ref. 41). Under this partnership, DHHS' National Center for Health Statistics is responsible for the sample design and data collection and USDA's Food Surveys Research Group (FSRG) is responsible for the data collection methodology and maintaining the food and nutrient database (i.e., the Food and Nutrient Database for Dietary Studies (FNDDS)) (Ref. 42), which is used for the survey. The WWEIA provides gram amounts of each food reported consumed in the past 24-hours (24-hour recall) from each survey participant. More details of the survey design procedure can be found in the NHANES Data (Refs. 41 and 43).

We analyzed the recent consumption by combining data from the survey years of the NHANES, 2003–2004, 2005–2006, and 2007–2008 (NHANES 2003–2008 surveys) using Statistical Analysis Systems (SAS) and Survey Data Analysis (SUDAAN) procedures (Refs. 44 and 45) which provide a current indication of the amount of food being consumed by individuals (Ref. 46). Food consumption data from the NHANES–WWEIA surveys are released in 2-year cycles. Since the survey of 2003–2004, there are two, 24-hour recalls of food intake data (day 1 and day 2) available for each survey participant and recall of intake data are collected using the USDA AMPM (Ref. 47). The AMPM is designed to provide an efficient and accurate way of collecting dietary intake data for a large-scale national survey (such as NHANES) based on a 5-step probing technique for extensive compilation of standardized food-specific questions and possible response

options (Ref. 47). USDA's validation study showed that AMPM provides an acceptable accuracy of collecting reported intake data by comparing the estimated calorie intake with total energy expenditure, and estimated protein intake with urinary nitrogen excretion as measured by the doubly-labeled water method (Refs. 48 and 49). In our analyses, we used data to determine the median and mean estimates of consumption (in grams or in household measurements) for the food products in the 140 product categories for the three population groups: Infants up to 12 months of age, children 1 through 3 years of age, and the general population of persons 4 years of age or older (Ref. 46). For the bakery products that were in ''as-consumed'' form (e.g., toasted bread), we multiplied by a factor of 1.1 or 1.2 to convert the consumption amount to an ''as-purchased'' form (e.g. untoasted bread) and those foods were then included in the analysis. The factor is the ratio of the moisture content between the foods in an ''as-purchased'' to ''as-consumed'' form due to loss of water during the toasting process. The factor was necessary in order to determine the consumption amount of bakery products in the form that is listed in table 2 in § 101.12(b).

Steps and Factors Used in Determining the Need to Update the 1993 RACCs (Ref. 50)

Step I—Evaluate Whether To Consider Updating the 1993 RACCs

Under Step I, FDA considered two factors. Under this step, if both of these factors were not met, FDA did not consider updating the 1993 RACC.

(1) 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 adequate sample size was determined based on the design effect of the data source for the analyses (Ref. 50). The design effect [5] is calculated using the ratio of the variance of the estimate that is based on a sample weighted design to the variance of the estimate based on a simple random sample by products within a product category (Ref. 50). This is necessary because NHANES uses a complex, stratified, probability survey design for data collection, which is a cost-saving data collection method often used for population surveys, rather than a simple random sampling method.

The data collection for NHANES, which is completed by CDC, is used to assess intake by the U.S. population; a purpose that differed from our purpose of updating RACCs. Therefore, 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. Therefore, 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 for those products.

(2) 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. Thus, we compared the median intake estimate from the NHANES 2003–2008 consumption data with the 1993 RACCs to determine if there was a at least a 25 percent difference (i.e. a significant difference) from the current RACCs. We used the median estimate of the intake distribution because it represents the central tendency of the amount customarily consumed per eating occasion. Also, the median is less influenced by outliers than the mean. In addition, we used a statistically conservative approach when considering the difference between the median intake estimate and the 1993 RACC for a product, to provide a 90 percent confidence level, with a 20 percent margin of error, to determine whether significant differences occur when the 95 percent confidence intervals of the consumption amount from the NHANES 2003–2008 surveys is outside of the 25 percent range (± 25 percent) of the RACCs established in 1993 (Ref. 50). In other words, 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 0.75 of the RACC or more than 1.25 of the RACC), we concluded that the current consumption amount is significantly different than the RACCs established in 1993. We chose the 25 percent approach based on our analysis of the data and after evaluating other values for percentage differences (e.g. 5%, 10%), when applied to the data, to reach a reasonable conservative estimate based on statistical principles. We further evaluated a product in Step II below if we found at least a 25 percent difference in consumption from the product in Step I. For a product for which there was not at least a 25 percent difference in consumption, we did not consider updating the 1993 RACC.

Step II—Determine Whether the 1993 RACCs Need To Be Updated

When a product had an adequate sample size to provide a reliable median intake estimate and this amount was significantly different than the 1993 RACC for the product, we then considered the factors below in a step-wise process to determine whether to update the 1993 RACCs:

(1) The Skewness of the Intake Distribution

We compared the median intake estimate from the NHANES 2003–2008 consumption data for the product consumed with the mean intake estimate from the NHANES 2003–2008 consumption data to determine whether the distribution of intake was skewed (Ref 48). A skewed intake distribution suggested that an empirical number of the reported consumption amounts were inconsistent and therefore, the variability between the mean and median estimates was considered to be large. The median intake estimate could not by itself provide sufficient evidence for the amount customarily consumed of that product by the United States target population if the intake distribution was skewed.

(2) The Reasonable Consumption Amount

If the intake distribution was skewed and we could not rely on the median intake estimate from the NHANES 2003–2008 consumption data as the sole basis to propose a change in the RACC, we examined the data from the FNDDS 4.1 (Ref. 42). 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. 42). If the reasonable consumption

[5] The design effect of the survey is a sample size adjustment compared to the survey if it would have been completed using a simple random sampling method. For example, if the design effect of a survey is 3, this means that the sample variance is 3 times larger than it would be if the data collection for the survey was based on a simple random sampling method. In other words, only one-third as many sample cases would be needed to measure the given statistic if a simple random sampling method were used instead of the cluster survey sampling method with a design effect of 3.0.

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, we then looked at if there was a significant difference between the median intake estimates from the NHANES 2003–2008 consumption data for the product, converted to a common household measure as applicable, and the 1993 RACC for the product.

(3) The Difference Between the Median Intake Estimates, Converted to Common Household Measures as Applicable, With the 1993 RACC for the Products

If we determined, based on our analysis, that the distribution of the intake of a product was not skewed, or skewed and not consistent with the reasonable consumption amount, we next compared the median intake estimate from the NHANES 2003–2008 consumption data for the product, converted to a common household measure as applicable, with the 1993 RACC for the product.

If the median intake estimate from the NHANES 2003–2008 consumption data for the product, converted to a common household measure as applicable, was not significantly different from the 1993 RACC for the product, we did not propose to update the 1993 RACC. This sometimes occurred when we converted the median intake estimate from the NHANES 2003–2008 consumption data to determine the common household measurement. If the converted median intake estimate from the NHANES 2003–2008 consumption data was significantly different from the 1993 RACC for the product, we used other considerations to determine whether the 1993 RACC should be changed.

(4) Other Considerations When the Median Intake Estimate From the NHANES 2003–2008 Consumption Data Is Significantly Different From the 1993 RACC for the Product

If there was no other comparable product with a median intake estimate from the NHANES 2003–2008 consumption data, we considered whether the estimated median intake from the NHANES 2003–2008 consumption data for the product was consistent with the reasonable consumption amount. If the median intake estimate from the NHANES 2003–2008 consumption data was consistent with the reasonable consumption amount, we proposed to update the 1993 RACC based on the median intake estimate from the NHANES 2003–2008 consumption data; otherwise, we considered each food product case-by-case to determine whether to change the 1993 RACC.

If there were comparable products with median intake estimates from the NHANES 2003–2008 consumption data, we considered these other comparable products to determine on a case-by-case basis whether to change the RACC for the product so that comparable products have the same RACC. In general, if multiple products were represented in a product category, we attempted to maintain a consistent RACC so that products with similar dietary usage (e.g., hot breakfast cereals, hominy, and grits are often used as breakfast items), similar product characteristics, and similar amounts customarily consumed could be easily compared. Similarly, we considered it beneficial to generally use the same RACCs for products that are in different product categories, when the products have similar amounts customarily consumed, similar dietary usage, and similar product characteristics (e.g., the ''All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips,) grain-based snack mixes'' product category and the ''Crackers that are usually used as snacks'' product category). Again, this is intended to help consumers to more easily compare nutrition information on the Nutrition Facts label across product categories. If the median intake estimate from the NHANES 2003–2008 consumption data for products in a product category varied, we gave greater consideration to the product that had the largest sample size (i.e., was consumed most frequently) in that product category when proposing a change to the 1993 RACC because there were more eating occasions reported by consumers for that product.

While we have taken a conservative approach in the methodology used to determine which RACCs should be updated, we recognize that there may be other methods that could be used. We invite comment on our analysis and rationale, and request data and factual information on alternative methodologies that we should use for determining which RACCs to update.

c. Proposed Amendments To Update the Existing RACCs

Using the methods described above, we propose to change the current RACCs used to determine the serving size for those products where consumption has changed significantly when compared to the RACCs established in 1993. These changes, if finalized, will be reflected in Table 1 ''Reference Amounts Customarily Consumed Per Eating Occasion: Foods for Infants and Children 1 through 3 years of age'' and Table 2 ''Reference Amounts Customarily Consumed Per Eating Occasion: General Food Supply'' of § 101.12(b).

Detailed information about how the principles, factors and steps were applied to change or not change the RACCs for specific food products is provided in a memorandum (Ref. 50). We analyzed consumption data for all 129 product categories in Table 2 in § 101.12(b) for persons 4 years of age or older and for the 11 product categories in Table 1 (§ 101.12(b)), for infants and children 1 through 3 years of age (Ref. 50). The proposed amendments that follow in this section are for food products where consumption has increased or decreased by at least 25 percent when compared to the RACCs established in 1993. Proposed amendments for food products where consumption has not increased or decreased by at least 25 percent when compared to the RACCs established in 1993 are provided in section II.D.3.b.

Changes to Table 1: Reference Amounts Customarily Consumed Per Eating Occasion: Food for Infants and Children 1 Through 3 Years of Age in § 101.12(b)

In the product category ''Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type'' we are proposing to change the RACC to 110 g from 60 g. The median consumption for desserts, ready-to-serve, strained type was 103 g and dinners, ready-to-serve, strained type was 104 g. The median consumption for fruits and vegetables, ready-to-serve, strained type was about 70 g. Products in this product category have similar dietary usage and product characteristics to the products in the ''Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type'' product category. We are proposing to change the RACC to 110 g, which would allow for consumers to make easy comparisons of nutrition information.

Changes to Table 2: Reference Amounts Customarily Consumed per Eating Occasion: General Food Supply in § 101.12(b)

In the general category of ''Bakery products,'' we propose to remove ''bagels,'' ''toaster pastries,'' and ''muffins'' from their current product categories, and to create a new product category for ''Bagels, toaster pastries, muffins (excluding English muffins),'' with a proposed RACC of 110 g compared to the current RACC of 55 g that was used for all of those food

products. This change is being proposed because the amounts customarily consumed in recent consumption data for these products are much higher than the amounts customarily consumed for the other products in their current product categories (i.e., the product categories established in 1993). Additionally, bagels, toaster pastries, and muffins (excluding English muffins) have similar product characteristics and dietary usage (e.g., they are products that can be used as breakfast products). The median consumption amounts for bagels, toaster pastries, and muffins are 104 g, 97 g, and 105 g, respectively. The median consumption amounts for those products are close to the reasonable consumption amount of one medium muffin, and the weight in grams of one regular-sized bagel.

In the general category of ''Beverages,'' we propose new RACCs of 360 mL and 360 mL for ''Carbonated and noncarbonated beverages, wine coolers, water'' and ''Coffee or tea flavored and sweetened,'' respectively, compared to the current RACCs of 240 mL and 240 mL prepared because current median intakes are 360 mL (or 12 fluid ounces) for these products. We also propose to change the label statements for these product categories within the general category of ''Beverages'' to 12 fl oz (360 mL) from 8 fl oz (240 mL). The consumption data for milk, fruit juices and vegetable juices remained unchanged from the current RACC of 240 mL. In the 1991 proposed serving size rule, we stated that a uniform RACC for all beverages would help consumers make nutritional comparisons across beverage categories (56 FR 60394 at 60407). While this is true, we still must base the RACCs on the amounts customarily consumed, and current data show that consumption amounts of carbonated and non-carbonated beverages, wine coolers, water, and coffee or tea flavored and sweetened are much greater than consumption amounts for milk, fruit juices, and vegetable juices. In addition to the consumption amounts being dissimilar, the product characteristics are somewhat different between milk, fruit juice, and vegetable juice compared to carbonated and non-carbonated beverages, wine coolers, water, and coffee or tea flavored and sweetened, because they are inherently nutrient dense (unlike carbonated and non-carbonated beverages, wine coolers, water, and coffee or tea flavored and sweetened). For these reasons we are not proposing to change the current RACC of 240 mL for milk, fruit juices, nectars, fruit drinks, and vegetable juices.

In the general category of ''Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes,'' we propose a new RACC of 85 g for the ''Fish, shellfish or game meat, canned'' product category, compared to the current RACC of 55 g because the median intake estimate from the NHANES 2003–2008 consumption data is approximately 85 g.

In the general category of ''Fruits and Fruit Juices,'' we propose a new RACC of 50 g for the product category of ''Fruits used primarily as ingredients, avocado'', compared to the current RACC of 30 g because the median intake estimate from the NHANES 2003–2008 consumption data for avocado is 50 g, and avocado is often used as an ingredient (e.g., in salads and sandwiches), similar to the product category ''Fruits used primarily as ingredients, others (cranberries, lemon, line)'' for which we are also proposing a new RACC of 50 g. Proposing a new RACC of 50 g for the ''Fruits used primarily as ingredients, avocado'' product category would help consumers easily compare nutrition information between all fruits used primarily as ingredients.

In the general category of ''Fruits and Fruit Juices,'' we propose a new RACC of 50 g for the product category of ''Fruits used primarily as ingredients, others (cranberries, lemon, lime)'' compared to the current RACC of 55 g. Because of the large variation between mean and median intake estimates from the NHANES 2003–2008 consumption data, we looked at the reasonable consumption amount for the products in the product category. The reasonable consumption amount for this product category is 50 g. Products in this product category are comparable to the product category ''Fruits used primarily as ingredients, avocado,'' which we are proposing a new RACC of 50 g. Proposing a new RACC of 50 g for the ''Fruits used primarily as ingredients, others (cranberries, lemon, lime)'' product category would help consumers easily compare nutrition information between all fruits used primarily as ingredients.

In the general category of ''Sugars and Sweets,'' we propose a new RACC of 30 g for the ''All other candies'' product category compared to the current RACC of 40 g. The median consumption amount for this product category was 22 g and the mean was 33 g. Because intake distribution is not considered skewed and there is no comparable product with a reliable median intake estimate from the NHANES 2003–2008 consumption data, we looked at data from the FNDDS (Ref. 42) on the reasonable consumption amounts of candies other than baking candies; hard candies, breath mints; hard candies, roll-type, mini-size in dispenser packages and hard candies. The reasonable consumption amount ranges from 14 to 59 g with the majority of the reasonable consumption amounts being 28 g. Therefore, given the variance in the median and mean we rounded the reasonable consumption amount of 28 g up to 30 g, which can be easily converted to a convenient household measure of one ounce for the proposed RACC for ''All other candies.'' We are also proposing to change the label statement to ____ pieces (____ g); 1 oz (30 g/visual unit of measure) for bulk products.

In the general category of ''Sugars and Sweets,'' we propose a new RACC of 8 g for the ''Sugar'' product category compared to the current RACC of 4 g. The median intake estimate from the NHANES 2003–2008 consumption data for sugar is 8 g.

In the general category of ''Sugars and Sweets,'' we propose a new RACC of 30 mL for all syrups in the ''Syrups'' product category, compared to the RACC of 30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup) and 60 mL for all others because the median intake estimate from the NHANES 2003–2008 consumption data for all syrups is 2 tablespoons (tbsp), which is close to 30 mL. We also propose to change the label statement for all Syrups to 2 tbsp (30 mL) from 2 tbsp (30 mL) for syrups used primarily as an ingredient; ¼ cup (60 mL) for all others.

3. Modifying and Establishing RACCs

This section discusses changes we are proposing that modify or establish RACCs. Since the final rule on serving sizes published in 1993, we have received requests from manufacturers to modify RACCs for products currently listed in the tables in § 101.12(b), establish RACCs for products not currently listed in the tables in § 101.12(b) and identify appropriate product categories for various food products (i.e., establish a RACC for that food product). These requests have come through various forms, including four citizen petitions referenced in section I.D.3., requests by manufacturers, and public comments to the ANPRM. In this section, we also propose to modify some product categories, on our own initiative, so that comparable products are grouped together. Thus, this proposed rule would establish certain RACCs for

products not currently listed in the tables in § 101.12(b) (in some cases by placing a product in a new product category with a new RACC, and in other cases by placing a product in an existing product category), and would modify RACCs for some existing products.

a. Methods Used To Modify Existing RACCs and Establish New RACCs

The products in this category are either new products for which no RACC is currently established, or products for which RACCs are currently established, but for which there has not been a significant increase or decrease in consumption (i.e., an increase or decrease in consumption representing a 25 percent difference) when compared to the RACCs established in 1993 (Ref. 50). Some products discussed below are ingredients of foods or other food products that are not available in the NHANES database. When determining where to place food products and what their RACCs should be, we looked first to the NHANES database, using similar methods to those used to update the 1993 RACCs, as described previously in this document. We analyzed recent consumption from the NHANES 2003–2008 surveys, when available, using SAS and SUDAAN procedures (Refs. 44 and 45). The factors considered when looking at NHANES 2003–2008 consumption data included: (1) The sample size and the median intake estimate from the NHANES 2003–2008 consumption data, and the mean intake estimate from the NHANES 2003–2008 consumption data (unlike the methods used to update the RACCs, the mean estimate was used as a guide when the median estimate was not available), (2) the difference between the NHANES 2003–2008 consumption data, converted to a common household measure as applicable, and the 1993 RACC for the product, (3) the reasonable consumption amount, (4) information received in manufacturers' requests, public comments, and (5) the NHANES 2003–2008 consumption data for comparable products and the largest sample size from the NHANES 2003–2008 consumption data within a product category. Detailed information about how these factors were applied to individual products is provided in a memorandum to the file (Ref 48).

If the food product was not available in the NHANES database, we looked to the main dietary usage of the product to determine if the product could fit into an existing product category. For accuracy and consistency in determining dietary usage, we used a culinary reference book entitled ''Food Lover's Companion,'' which has been used by nutrition professionals as a food dictionary reference (Ref. 51), and internet resources with extensive recipe collections such as, *http://www.allrecipes.com, http://www.food.com,* and *http://www.recipe.com* (Refs. 52, 53 and 54). Market data (e.g., Neilson sales data) were used to examine the top selling products. Additionally, the Gladson and Mintel databases, which provide labeling information for products that are currently available in the market, were used to look at industry practice (Refs. 55 and 56). For foods that are used as ingredients, the RACCs are generally determined based on the amount of the ingredient that is needed to prepare the finished product per eating occasion (e.g., cocoa powder, unsweetened is used as an ingredient for chocolate cakes). For all products in this section, we considered additional data sources, such as data from the gram weight information for various portion sizes based on the National Nutrient Database for Standard Reference, release 24 (Ref. 57), recipe information from FNDDS, a guidance document entitled ''Guidance for Industry: A Food Labeling Guide'' (Ref. 58), and other federal guidance documents (Ref. 59).

b. Proposed Amendments To Modify Existing RACCs and Establish New RACCs

In this section we propose to modify RACCs, establish RACCs, and place products in appropriate product categories in Table 2 in § 101.12(b).

In the general category of ''Bakery products,'' we propose to:

1. Add ''scones, crumpets, and English muffins'' to the current product category ''Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies'' with a RACC of 55 g. The new name for this product category would be ''Biscuits, croissants, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies, scones, crumpets, and English muffins'' (as discussed in section II.D.2.c., we also are proposing to move bagels to a new product category). Currently there is no RACC for scones and crumpets. The median intake estimate from the NHANES 2003–2008 consumption data for scones and crumpets is 37 g. The reasonable consumption amount of one scone with or without fruit is 42 g, and one crumpet weighs 45 g. The median intake estimate from the NHANES 2003–2008 consumption data for biscuits and croissants is 51 g and 57 g, respectively. Biscuits and croissants have a larger sample size compared to scones and crumpets. Biscuits, croissants, scones, crumpets and English muffins are comparable to other products in this category and can be used as breakfast bakery products. Therefore, based on these factors, we propose to add scones, crumpets, and English muffins to the current product category ''Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies'' with a RACC of 55 g; and

2. Add to proposed footnote 5 that the serving size for fruitcake is 1½ oz. Fruitcake belongs in the ''Cakes, heavy weight'' product category, which has a RACC of 125 g, because it is generally 18 g per cubic inch, which meets the 10 g or more per cubic inch weight minimum for this category (see current footnote 6 in table 2 of § 101.12(b)). The NHANES 2003–2008 surveys have limited consumption data for fruitcake because there are only 24 eating occasions for fruitcake from NHANES 2003–2008 surveys. The fruitcake petition requested a new RACC for fruitcake and noted that fruitcake is a specialty item consumed primarily over the holidays and that the industry has traditionally, before mandatory nutrition labeling was implemented, used 1½ oz as the serving size. We propose to add to proposed footnote 5 that the serving size for fruitcake is 1½ oz because: (1) It is a specialty item consumed primarily over the holidays; and (2) industry has traditionally used 1½ oz as a serving size; and

3. Establish a new product category ''Eggroll, dumpling, wonton, or potsticker wrappers'' with a RACC of 20 g. The proposed label statement is ''____ sheet (g)'' or ''____ wrapper (g).'' Wrappers for eggrolls, dumplings, wontons, or potstickers are generally used as ingredients to make eggrolls, dumplings, wontons, and potstickers. Eggrolls, dumplings, wontons, and potstickers are used primarily as appetizers. Generally about 1 eggroll, 5 wontons, and 3 potstickers will make 1 serving of an appetizer with a RACC of 85 g (as discussed in this section of the document, we are proposing a new product category for appetizers with a RACC of 85 g). The amount of wrappers that are needed to make 1 serving of an appetizer with a RACC of 85 g is about 20 g; and

4. Add ''crepes'' to the product category ''French toast, pancakes, variety mixes,'' with a RACC of 110 g prepared for French toast, crepes, and pancakes and 40 g dry mix for variety mixes. The new name for this product category would be ''French toast, crepes, pancakes, variety mixes.'' The median consumption for crepes is 101 g, and crepes are comparable products to pancakes and French toast (e.g.,

breakfast bakery products) and are similar to pancakes without the leavening ingredients that are used in pancakes; and

5. Add ''pie shell'' and ''pastry sheets'' to the product category ''Pie crust'' and modify the RACC to be ''the allowable declaration closest to an 8 square inch surface area.'' The new product category name would be ''Pie crust, pie shell, pastry sheets (e.g., phyllo, puff pastry sheets).'' We recognize a need to establish additional reference amounts for crusts to provide a basis for determining serving sizes for crusts and shells with diameters other than 8 or 9 inches. We also propose to change the label statement for this product category to ''____ fractional slice(s) (____ g) for large discrete units; ____ shells (____ g); ____ fractional ____ sheet(s) (____ g) for distinct pieces (e.g., Pastry sheet).'' An example of a label statement for pastry sheets would be ⅙ of 1 sheet (____ g). This modified product category would include, for example, miniature crusts, phyllo pastry sheets, puff pastry, and pie crusts with a diameter of 10 inches. Changing the RACC would make the crust and shell category consistent with the way that pies are treated in this product category, such that the fraction of the total pie will be equal to the same fraction of the crust or shell plus filling. In the case of small individual units, the serving size would be the same number of units whether filled or unfilled. Pie shells and pastry sheets have similar dietary usage to pie crusts as an ingredient of dessert products.

In the ''Dairy Products and Substitutes,'' general category, we are proposing to:

1. Change the name of 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'' with a RACC of 240 mL. We are adding milk-substitute beverages to this product category because milk and milk-substitute beverages are comparable products and consumers can make nutrition information comparisons among these products. Nutritionally equivalent (see § 101.3(e)(2)) soy beverages are an example of milk-substitute beverages and can be used as a substitute for milk (Ref. 51).

2. Change the RACC of the product category ''Yogurt'' to 170 g, which is approximately 6 oz. The current RACC for yogurt is 225 g or approximately 8 oz. The NHANES 2003–2008 consumption data show the median consumption for yogurt is about 6 oz, but did not meet the 25 percent change level we are using in this proposed rule as a factor to consider whether to update the RACCs. However, comments on the ANPRM from the yogurt industry and the NYA citizen petition have requested that we change the RACC for yogurt to reflect what is the most commonly consumed in the market place. In addition, 2009–2010 AC Nielson sales data has 6 oz containers of yogurt ranked highest among annual sales data for yogurt. We have decided to change the RACC for yogurt based on current consumption data, information in the NYA citizen petition, information from industry comments on yogurt consumption, and market trends.

In the general category of ''Desserts'' we propose to:

1. Change the name of the product category ''Ice cream, ice milk, frozen yogurt, sherbet: All types, bulk and novelties (e.g., bars, sandwiches, cones)'' to ''Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: All types bulk'' and change the RACC for this product category to 1 cup, as compared to the current RACC of ½ cup. We also propose to change the label statement for this product category to ''1 cup (____ g).'' This new product category would not include ice cream novelties because ice cream novelties are not comparable to the other products in this product category. Ice cream novelties are often prepackaged and come in multiple individual units per package. We received comments on the ANPRM stating that the RACC for ice cream is ''unrealistic and misleading.'' The comments stated that a ½ cup of ice cream is smaller than a household ice cream scoop and should be increased to an amount people normally consume. Current 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. Bulk ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices are all comparable products and are usually all sold in the same area of the grocery store. We propose to change the RACC to 1 cup although, based on the calculations from the current consumption data, the products in the original product category (which included ice cream novelties) generally did not change by at least 25 percent; and

2. Change the name of the product category ''Frozen flavored and sweetened ice and pops, frozen fruit juices: All types, bulk and novelties (e.g., bars, cups)'' to ''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)'' and change the RACC for this product category to ''½ cup—includes the volume for coatings and wafers,'' as compared to the current RACC of 85 g. We changed the RACC from a weight measurement (grams) to a volume measurement (cups) because of the difference in density between various ice creams, frozen flavored and sweetened ice and pops, frozen yogurts, and sherbets. For example, 1 cup of ice cream generally weighs about 133 g, while 1 cup of frozen yogurt generally weighs 200 g, and 1 cup of ice pop generally weighs 254 g. However, the median consumption for all of these products is ½ cup regardless of weight. The new product category will include ice cream, ice milk, frozen yogurt, and sherbet novelties. Current consumption for ice cream sandwiches, bars and cones is 68 g (about ½ cup) and for frozen yogurt cones is 78 g (about ½ cup), which is similar to the consumption data for frozen flavored novelties. Ice cream, ice milk, frozen yogurt, and sherbet novelties are more comparable with frozen flavored novelties than they are with bulk ice creams, ice milks, frozen yogurts, and sherbets; and are usually sold in the same area of the grocery store as the other products listed in this product category; and

3. Change the RACC for the product category ''Custard, gelatin, or pudding'' to ''½ cup prepared; Amount to make ½ cup prepared when dry.'' The current RACC for this category is ''½ cup.'' Custard powder, gelatin, and pudding powder are often used to make custard, gelatin, and pudding desserts. There is currently a RACC for the prepared version of these products, but not the dry form used in preparation mixtures.

In the general category of ''Dessert Toppings and Fillings'' we propose to:

1. Change the weight-based RACC for the product category of ''Cake frostings or icings'' with a RACC of 35 g to a volume-based RACC of 2 tbsp. The RACC of 35 g does not take into account whipped frosting and icings that may not weigh 35 g. Changing to a volume based reference amount would allow for consistency in the category and allow comparison of nutrition information for these products based on the same RACC.

In the general category of ''Egg and Egg Substitutes'' (proposed to be renamed as the general category of ''Egg and Egg Substitutes'' as discussed as follows), we propose to:

1. Change the name of the product category ''Egg Substitutes'' (which has a RACC of ''An amount to make 1 large

(50 g) egg'') to ''Egg whites, sugared eggs, sugared egg yolks, and egg substitutes (fresh, frozen, dried).'' The median consumption for egg white, sugared egg, and sugared egg yolk is 64 g. Egg white, sugared egg, and sugared egg yolk are comparable products and can be used as a substitution of a whole egg.

In the general category of ''Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes,'' we propose to:

Add ''seafood'' to the product category ''Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters,'' which has a RACC of 55 g. The median consumption for seafood substitutes is 60 g. The new name for the product category would be ''Substitute for luncheon meat, meat spreads, Canadian bacon, sausages, frankfurters, and seafood.'' Seafood substitutes are comparable products to other products in this product category.

In the current general category of ''Miscellaneous Category'' (proposed to be renamed as the general category of ''Miscellaneous'' as discussed in section II.F.3.), we propose to:

1. Establish a new product category for ''Cocoa powder, carob powder, unsweetened'' with a RACC of 1 tbsp. The proposed label statement is 1 tbsp (____ g). Unsweetened cocoa powder or baking cocoa is a dry, unsweetened, chocolate-flavored powder that is often used as an ingredient in various recipes, including cakes, brownies, and cookies. Because it is an ingredient, there is no direct consumption data from the NHANES 2003–2008 surveys. Carob powder is used as a substitution for unsweetened cocoa powder in baking; thus, it has similar dietary usage to unsweetened cocoa powder (Ref. 51). Examining a variety of chocolate cake recipes (Ref. 52), the weight of baking cocoa powder ranges from 3 g to 5 g to make a reference amount of 55 g for chocolate cake without icing or filling; and

2. Change the name of the product category ''Drink mixers (without alcohol)'' to ''Milk, milk substitute, and fruit based drink mixes (without alcohol): (e.g., drink mixers, fruit flavored powdered drink mixes, sweetened cocoa powder)'' with a RACC of ''Amount to make 240 mL drink (without ice).'' The NHANES 2003–2008 consumption data show that the median intake estimate for milk-substitute beverages is 184 g (about 6 fl oz). Based on the Gladson database, the majority of products are using 8 fl oz or 1 cup as the serving size on the label. This proposed RACC is the same as the RACC for comparable products (i.e., milk, milk-based drinks, fruit juices, and fruit drinks). This new product category includes products that were not included in the 1993 serving size final rule. The 1993 serving size final rule includes prepared versions of the products in this category, but not the dry forms used to make the prepared beverages. We propose to establish a label statement for this product category of ''____ fl oz (____ ml), ____ tsp (____ g), ____ tbsp (____ g)''; and

3. Establish a new product category ''Drink mixes (without alcohol): all other types (e.g., flavored syrups and powdered drink mixes'' with a RACC of ''Amount to make 360 mL drink (without ice).'' This new product category includes products that were not included in the 1993 serving size final rule. The 1993 serving size final rule includes prepared versions of these products in the ''Beverages'' general category, but not the dry forms used to make the prepared beverages. The current RACC for the ''Beverages'' general category is 240 mL. We are proposing to change the RACC for ''Beverages'' to 360 mL. The products in this proposed product category are comparable to the products in the ''Beverages'' general category. We also propose to establish a label statement for this product category of ''____ fl oz (____ mL), ____ tsp (____ g), ____ tbsp (____ g)''; and

4. Establish a new product category ''Seasoning oils and seasoning sauces (e.g., coconut concentrate, sesame oil, almond oil, chili oil, coconut oil, walnut oil)'' with a RACC of 1 tbsp. This product category includes flavorings, seasonings and spices that are in a liquid form and are primarily used as ingredients in a product, rather than as sauces or dips with finished foods. Coconut concentrate is an extract of the cooked mixture of water and coconut meat, which is often used as an ingredient of a sauce or dressing (such as curry sauce) (Ref. 51). The reasonable consumption amount for the flavoring oils (sesame oil, almond oil, coconut oil, and walnut oil) is 13.6 g (about 1 tbsp) based on the FNDDS (Ref. 42). We also propose to establish a label statement for this product category of 1 tbsp (____ g); and

5. Establish a new product category ''Seasoning pastes (e.g., garlic paste, ginger paste, curry paste, chili paste, miso paste, fresh or frozen)'' with a RACC of 1 teaspoon (tsp). This product category includes seasonings and spices that are in a paste form and are primarily used as ingredients (such as miso in making miso soup), rather than as sauces or dips for finished foods. The current median intake estimate is 4 g. The reasonable consumption amount for miso paste, which is an example product in this product category, is 3 g (about 1 tsp). We also propose to establish a label statement for this product category of 1 tsp (____ g).

In the general category of ''Mixed Dishes,'' we propose to:

1. Change the name of the product category ''Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches'' to ''Not measurable with cup, e.g., burritos, enchiladas, pizza, pizza rolls, quiche, sandwiches.'' We are proposing to include smaller sized versions of some of these products in a new appetizer product category. Smaller versions of these products are primarily used as appetizers, while products in the mixed dish category are primarily used as entrees or main dishes. We have updated the category name to reflect the change; and

2. Establish a new product category for ''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,'' with a RACC of 85 g, add 35 g for products with gravy or sauce topping. The new ''Appetizers, hors d'oeuvres, mini mixed dishes'' product category would contain products that are not included in table 2 of § 101.12(b). 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. 59), which provides a RACC of 85 g for ''Appetizers hors d'oeuvres, mini eggrolls, mini pizza rolls, bagel pizza with meat or poultry.'' The USDA products are mostly the same as the products being proposed in our new ''Appetizers, hors d'oeuvres, mini mixed dishes'' product category, except that the USDA products always contain meat. The median consumption for mini pizza rolls is 83 g and for egg rolls is between 57 and 59 g. Additionally, all of the products in this proposed ''Appetizers, hors d'oeuvres, mini mixed dishes'' product category are comparable in their usage. Therefore, we propose a RACC of ''85 g add 35 g for products with gravy or sauce topping'' for this product category, which is consistent with USDA's RACC for ''Appetizers hors d'oeuvres, mini eggrolls, mini pizza rolls, bagel pizza with meat or poultry,'' which will allow consumers to compare nutrition information across food labels for these types of products. The addition of 35 g sauce is calculated proportionally by the

weight of the RACC for the product category ''Mixed Dishes not measurable with cup'' where the addition of 55 g of sauce is used for the 140 g of RACC. We propose that an individual unit in this new product category should not weigh more than 85 g, or it would not be considered an appetizer, hors d'oeuvre, or mini mixed dish. For example, if an individual eggroll were to weigh more than 85 g, it would be appropriate to use the RACC from the general category ''Mixed Dishes'' and the product Category ''Not measurable with cup.'' We also propose to establish a label statement for this product category of ____ pieces(s) (____ g).

In the general category of ''Sauces, Dips, Gravies and Condiments,'' we propose to:

1. Add ''Alfredo sauce'' to the product category ''Minor main entrée sauces (e.g., pizza sauce, pesto sauce)'' with a RACC of ¼ cup. The new product category name would be ''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.'' Alfredo sauce is mixed with and coats a pasta product (Ref. 51). This dietary usage is similar to that of pesto sauce in the ''Minor main entrée sauces'' product category.

In the general category of ''Soups,'' we propose to:

1. Establish a product category ''Dry soup mixes, bouillon.'' The RACC for this category would be the ''Amount to make 245 g.'' Bouillon and dry soup mixes are often used to make soups and broths (Ref. 51). There is currently a RACC for the prepared version of these products, but not the dry form used in preparation mixtures. The RACC for soups is 245 g. We also propose to establish a label statement for this product category of ____ cup (____ g); ____ cup (____ mL).

In the general category of ''Sugars and Sweets,'' we propose to:

1. Establish a new product category ''After-dinner confectionaries'' with a RACC of 10 g. We reviewed consumption data from the NHANES 2003–2008 surveys to determine whether a change in the RACC for Andes mint wafers and other after-dinner confectionaries, as requested in the Andes petition, was warranted. These types of candies are currently included in the ''All other candies'' product category. Because there are no intake data available from the NHANES 2003–2008 surveys to determine intake estimates for after-dinner confectionaries, we relied on industry product information available through the Gladson and Mintel databases (Refs. 55 and 56). These databases are comprehensive and include label information for products currently on the market. The databases indicated that products marketed as ''after-dinner confectionaries'' or comparable candy products ranged in weight from approximately 2 to 12 g per piece. According to the serving size information on after-dinner confectionary product labels in the Gladson and Mintel databases, the weight of an individual piece varies considerably among the different products in this category. To avoid having the serving size of the larger size products expressed as a faction of a piece, we propose that all products marketed as after-dinner confectionaries (or after-dinner mints) should have the same RACC of 10 g, which is slightly smaller than the 15 g RACC requested in the Andes petition. We also propose to establish a label statement for this product category of ____ piece(s) (____ g);

2. Add ''powdered candies'' and ''liquid candies'' to the product category ''Hard candies, others'' with a RACC of 15 mL for liquid candies and 15 g for all others. We propose to rename the product category to ''Hard candies, others; powdered candies, liquid candies'' to indicate that powdered and liquid candies would be added to this product category. After publication of the 1993 serving size final rule, two manufacturers asked that powdered candies, which are frequently sold in straws or small packets, be included in the ''Hard candies, others'' product category with a RACC of 15 g (Refs. 9 and 10). One manufacturer also asked to classify liquid candy (which is very sweet and frequently sold in wax containers containing syrup or flavored liquid) in the ''Hard candies, others'' product category with a RACC of 15 mL. The manufacturers stated that 15 g (or 15 mL) was a more reasonable RACC than 40 g in the ''All other candies category.'' We suggested that manufacturers use a RACC of 15 g for flavored and colored powdered candies and 15 mL for syrup-filled wax liquid candies (Refs. 60 and 61). In ''Guidance for Industry: A Food Labeling Guide'' (Question L62), we listed 15 g as the suggested RACC for powdered, flavored candy and 15 mL as the suggested RACC for colored, flavored syrup-filled wax candy (Ref. 58). There are no median intake estimates for either powdered or liquid candies and the mean intake estimate for liquid candies is 13 g in the NHANES 2003–2008 surveys. Based on product label information from the Mintel database, 15 g has been used for various powdered candy products, and 20 mL has been used for wax candies. Because powdered and liquid candies are used comparably, we propose to establish RACCs of 15 g for powdered candies and 15 mL for liquid candies and to add them to the ''Hard candies, others'' product category. These are the same RACCs we suggested in 1993 that manufacturers should use, and which are listed in our ''Guidance for Industry: A Food Labeling Guide'' (Question L62) (Ref. 58). We also propose to establish a label statement ____ piece(s) (____ g) for large pieces; ____ tbsp(s) (g) for ''mini-size'' candies measurable by tbsp; ____ straw(s) (____ g) for powdered candies; ____ wax bottle(s) (____ mL) for liquid candies; and 1/2 oz (14 g/visual unit of measure) for bulk products; and

3. Add ''fruit paste and fruit chutney'' to the product category ''Honey, jams, jellies, fruit butter, molasses'' with a RACC of 1 tbsp. The new product category name would be ''Honey, jams, jellies, fruit butter, molasses, fruit paste, fruit chutney.'' The current median consumption for fruit chutney and fruit paste is similar to the 1 tbsp RACC used for the product category ''Honey, jams, jellies, fruit butter, molasses.'' Fruit chutneys and fruit pastes have similar dietary usage to jams, jellies, and fruit pastes, as all can be used to spread on breads (Ref. 51).

In the general category of ''Vegetables,'' we propose to:

1. Change the name of the product category ''Chili pepper, green onion'' to ''Fresh or canned chili peppers, jalapeno peppers, other hot peppers, green onion.'' Jalapeno pepper and other hot peppers are comparable products to chili peppers;

2. Establish a new product category for ''Dried vegetables, dried tomatoes, sun-dried tomatoes, dried mushrooms, dried seaweed'' with a RACC of 5 g, add 5 g for products packaged in oil. We also propose to establish a label statement for this product category of ''____ piece(s); ⅓ cup (____ g).'' The median intake estimate from the NHANES 2003–2008 consumption data for dried vegetables is about 2 g and 6 g for dried tomatoes. One cup of dried seaweed weighs 15 g. Dried vegetables, dried tomatoes, sun-dried tomatoes, dried mushrooms, and dried seaweed are comparable products. Sun-dried tomatoes are dried tomatoes and are often packed in oil (Ref. 51). One tsp of oil weighs about 5 g;

3. Establish a new product category ''Dried seaweed sheets'' with a RACC of 3 g. We also propose to establish a label statement for this product category of ____ piece(s) (____ g); cup(s) (____ g). Industry uses 2.5 g to 3 g per sheet, with

one sheet per serving, on the product labels and the current suggested RACC for dried seaweed sheets is 3 g in our guidance ''Guidance for Industry: A Food Labeling Guide'' (Ref. 58); and

4. Establish a new product category ''Sprouts, all types: fresh or canned'' with a RACC of 10 g. The median intake estimate from the NHANES 2003–2008 consumption data for all sprouts, is 14 g. However, because there is a large variation in the density (i.e., the gram weight per cup) for various types of sprouts, we propose to establish a RACC of ¼ cup for this new product category. We also propose a label statement for this product category of ''¼ cup (____ g).''

We also considered modifying the RACCs for burritos, pizza and sandwiches. We note that burritos, pizza, and sandwiches appear to be commonly consumed products, as demonstrated by their relatively large sample sizes in the NHANES 2003–2008 surveys. The intake distributions for burritos, pizza, and sandwiches are not considered skewed, and although the median intake estimates from the NHANES 2003–2008 consumption data for burritos, pizza, and sandwiches products are 184 g, 172 g, and 170 g, respectively, they are not significantly different from the 1993 RACC of 140 g (Refs. 46 and 50). Therefore, we are not proposing to change to the 1993 RACC. However, the median intake estimates from the NHANES 2003–2008 surveys are higher for these products compared to the median intake estimates from the NHANES 2003–2008 surveys for other comparable products (e.g., Turnovers, 142 g; other mixed dishes, 149 g) in the same product category ''Mixed dishes not measureable with cup.'' Therefore, we invite comment on whether the current RACC for these products should be increased, and if so, by what amount.

4. Products of Concern Listed in Consumer Comments—Agency Request for Information

The majority of consumer comments on the ANPRM stated that the food labels on the following foods are misleading and recommended that the serving size be increased: 20 fluid oz bottles of carbonated beverages, canned soup, snack size packages of potato chips and pretzels (e.g., salty snacks), fruit juice, microwave popcorn, canned chili, shelled nuts, iced tea, TV dinners, energy drinks, canned ravioli, 5-inch pizzas, dairy beverages, pre-packaged lunches, vending machine items, breakfast cereals, macaroni and cheese, cookies, crackers, ice cream, coffee creamer and muffins. Most of these foods did not have a change in consumption of at least 25 percent, which is a factor we consider in this rule to update the RACC. Although the proposed rule would not change the RACC for most of these products, we feel that the comments' concerns have been addressed with the proposed definition of single-serving containers and the proposed requirements for dual-column labeling. The proposed requirements would allow for products that contain less than 200 percent of the RACC to be labeled as a single-serving container and for products that contain 200 percent and up to and including 400 percent of the RACC to be labeled with dual-column labeling that would provide nutrition information per serving and per container in the Nutrition Facts label. The majority of the products of concern listed above would meet either of the proposed requirements for single-serving containers or dual-column labeling.

We invite comment on whether we should change the RACC for foods in these categories due to consumer concern of misleading label information. If so, which foods should we change? What factor(s) should we use to determine when these foods should be changed? Are there any data available to support a change in the RACCs of these foods? Additionally, to the extent that some comments may be concerned about misleading package sizes when compared to labeled serving sizes, as opposed to being concerned with the appropriate serving size for specific food products within a product category, we invite comment on whether the proposed requirements for single serving and dual-column labeling alleviate the comments' concerns.

5. Impact of Changes in RACCs on the Eligibility of Nutrient Content Claims and Health Claims

We recognize that changes to the serving size regulations, especially updating the RACCs, could affect the eligibility of individual foods to bear nutrient content claims or health claims. The amount of a nutrient that is the subject of a nutrient content claim or health claim is typically calculated on a per RACC basis. For example, for individual foods (i.e., foods that are not meal products or main dish products) that have RACCs greater than 30 g or greater than 2 tbsp, to be eligible to bear a ''low fat'' nutrient content claim, the food must meet the criterion of 3 g of total fat or less per RACC (§ 101.62(b)(2)(i)(A)). Using the health claim on intake of sodium and reduced risk of hypertension as an example, the levels of sodium in an individual food eligible to bear the claim must meet the criterion of ''low sodium'' claim under § 101.61(b)(4), which contains specific requirements respecting maximum amounts of sodium per RACC for various foods eligible to bear the claim (see § 101.74(c)(2)(ii)).

We are 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. For example, an individual food with a total fat value of 3 g of total fat per ½ cup serving may have been eligible for a ''low fat'' claim with the existing RACC, but if the RACC increases to 1 cup, the food would have a total fat value of 6 g total fat per RACC and would no longer be able to be considered ''low fat.'' Additionally, we are aware that individual foods that are currently ineligible to bear certain claims may potentially become eligible to bear such claims if their RACCs change. For example, foods that are currently ineligible for a ''good source of calcium'' claim (§ 101.54(c)) at the current RACCs may be able to meet the specific criterion in the regulations if their RACCs increased in size, causing the food to have an accompanying increase in the calcium levels per RACC. Another example is that individual foods that are currently ineligible for a ''low sodium claim'' may be able to meet the specific criterion in the regulations if their RACCs are decreased in size, causing the food to have an accompanying decrease in the sodium levels per RACC.

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 as well. For example, the levels of total fat, saturated fat, cholesterol, and sodium that trigger the need for a disclosure statement for individual foods bearing a nutrient content claim are on a per RACC and per labeled serving basis (§ 101.13(h)). The disclosure levels for most foods are 13.0 g of total fat, 4.0 g of saturated fat, 60 mg of cholesterol, and 480 mg of sodium per RACC. Foods that currently bear nutrient content claims and do not exceed the disclosure values per RACC would not need to include any disclosure statement; however, if the RACC for that food were to increase, and values for total fat, saturated fat, cholesterol, or sodium per RACC were also to increase, the food may then potentially be required to bear a disclosure statement. Further, the same levels of total fat, saturated fat, cholesterol, and sodium per RACC that trigger the need for a disclosure

statement on certain products bearing nutrient content claims, also disqualify certain foods from making any health claims (§ 101.14(a)(4)). Therefore, an increase in a RACC with an accompanying increase in nutrient value per RACC could potentially disqualify that food from bearing a health claim. To bear a health claim, foods must also generally contain a minimum of 10 percent or more of the DV for one of the following nutrients: Vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (§ 101.14(e)(6)). Changes to the RACCs could affect whether a food is able to meet this requirement. An increase in a RACC could cause a food to be able to meet the minimum nutrient content requirement, while a decrease in a RACC could cause a food to have decreased nutrient values per RACC and potentially lose its' ability to bear a health claim based on minimum nutrient content requirements.

Although changes to the existing RACCs have the potential to impact individual foods' eligibility to bear nutrition claims, changes in the eligibility to bear claims may be appropriate in light of the changes in the amounts of food being customarily consumed. It is difficult to fully understand any potential impacts of changes to the RACCs on the eligibility to bear claims until such time that rulemaking for both serving sizes and updating the Nutrition Facts label are finalized. We are inviting comment on any concerns related to changes to current claims used on specific foods that will be affected if RACCs are finalized as proposed.

6. Request To Establish a New 25 g RACC for Candies Weighing 20 g or Less

As discussed in section I.D.3.e., two trade associations representing chocolate and confectionary companies jointly submitted a citizen petition (the CMA/NCA petition) to FDA. The petitioners requested that we amend the ''Sugars and Sweets'' general category by establishing a new 25 g RACC for candies (other than hard candies or baking candies) weighing 20 g or less per piece.

Because the national food consumption data (i.e., from the NHANES 2003–2008 surveys) upon which we primarily rely to establish RACCs generally does not capture data for different sizes of candy products, we cannot establish a new candy product category with a RACC of 25 g for candies weighing 20 g or less per piece, as requested in the CMA/NCA petition. NHANES is designed to provide total intake amounts per eating occasion for different types of products. If the total consumption amount of a chocolate candy bar was 100 g, we would not be able to discern whether this amount was derived from 1 large-size candy bar weighing 100 g, or from 10 mini-sized bars weighing 10 g each. Therefore, we do not have data to support basing the RACC on the weight of individual pieces of candy, as requested in the petition.

E. Establishing a New Serving Size for Breath Mints

As discussed in section I.D.3.F., we received a petition from a breath mints manufacturer requesting that we create a separate product category with a 0.5 g RACC for small breath mints (weighing 0.5 g or less). The petitioner also specified that the serving size for small breath mints should be ''one mint.'' In response to this petition, we published the 1997 breath mints proposed rule (62 FR 67775), which would require that the label serving size of products included in the product category ''Hard candies, breath mints'' be one unit. However, we determined that it would not be appropriate to establish a separate 0.5 g RACC for small breath mints because there was insufficient evidence for revising the current RACC of 2 g for breath mints. Because we are addressing issues related to the label serving size for breath mints, in conjunction with other serving size issues, in this proposed rule, we are withdrawing the 1997 breath mints proposed rule elsewhere in this issue of the **Federal Register**.

Consumption of breath mints cannot be determined using NHANES 2003–2008 consumption data, which provide the most recent national food consumption data available to us. This is because a specific category for breath mints does not exist in the FNDDS to process and analyze dietary intake data for the NHANES 2003–2008 surveys. Rather, breath mints are included as part of the large ''hard candy'' group (food code 91745020), which contains approximately 50 items. However, the reasonable consumption amount for breath mints in the FNDDS database is 2 g for one-piece breath mints. Further, based on the Mintel and Gladson databases (large commercial databases containing full product details on currently available product packages), we determined that the median estimate of the gram weight distribution of breath mints from these databases is 3 g and 2 g, respectively (Ref. 62). Therefore, we have determined that 2 g remains an appropriate RACC for the product category ''Hard candies, breath mints.''

Although the 2 g RACC for ''Hard candies, breath mints'' remains reasonable, we share concerns about the apparent inappropriateness of the resulting serving sizes on the labels of small and very small breath mints when the 2 g RACC is used to determine the serving size (e.g., 5 small breath mints or 15 very small breath mints per serving). The data submitted to us through the citizen petition suggests that these products were designed to be consumed singly or in small numbers and that consumers do, in fact, customarily consume such amounts (Docket No. FDA–1994–P–0314, formerly Docket No 94P–0168). Requiring the serving size on the label of all breath mints to be declared as one mint (or one unit) would more accurately reflect the amount customarily consumed across a wide variety of breath mint sizes that are commercially available.

Therefore, using a label statement of one unit for the serving size of all breath mints is more appropriate than declaring the serving size in terms of the number of mints closest to the 2 g RACC, because the RACC of 2 g for all breath mint products does not specifically represent the amount customarily consumed per eating occasion for small breath mints and very small breath mints. This action would allow for efficient enforcement of the FD&C Act by maintaining one subcategory in table 2 of § 101.12(b) for all breath mints, while requiring the label statement for the serving size to accurately reflect the amount customarily consumed. Thus, we are proposing to amend footnote 9 (which we are proposing to redesignate as footnote 8 in this rule) of table 2 in § 101.12(b) to state that ''Label serving size for ice cream cones, eggs, and breath mints of all sizes will be 1 unit . . .'' while keeping 2 g as the reference amount for the product category ''Hard candies, breath mints.''

F. Comparison of Calories in Foods of Different Portion Sizes

As noted in the ''Calories Count'' report (Ref. 1), the Federal Trade Commission has suggested that we consider ''allowing food marketers to make truthful, non-misleading label claims comparing foods of different portion sizes.'' An example of this type of claim would be: ''This 4 ounce container of yogurt has 25 percent less calories than our 6 ounce container of yogurt.''

In the ANPRM, we invited comment on whether it would be confusing to consumers to have claims made only on the basis of the difference in the amount

of calories in two different labeled serving sizes (i.e., the serving size specified in two different Nutrition Facts labels (e.g., an 8 fl oz can of soda versus a 12 fl oz can of soda) or two different portions (i.e., amounts specified by the claim, e.g., one 15 g cookie versus two 15 g cookies) of the same food. We also invited comment on other questions related to this issue, but we received no comments on these other issues.

Several comments indicated that we should not allow comparison of calories to be made among foods of different portion sizes as this would increase confusion. Some comments suggested that we increase consumer education on serving sizes instead. Other comments noted that basing differences in calories on two different label servings or two different portions would be confusing to consumers and serve no constructive purpose. One comment noted that calorie claims would probably be confusing to consumers on bulk-type packages, where consumers portion out their own serving. However, this comment noted that if claims were made on single-serving containers, where portion size is determined by the manufacturer, they could be less confusing and more helpful to consumers. The comment stated that calorie differences between choosing an 8 fl oz can of soda versus a 12 fl oz can of soda could be more apparent to consumers if comparison claims were allowed.

We agree with the comments that stated consumer education on serving sizes should be increased. We consider it appropriate to provide consumers with education and outreach on serving size issues and will consider appropriate education methods after publication of this proposed rule. At this time, we do not see the need to propose specific regulations for the use of calorie comparison claims, because our current regulations do not expressly prohibit such claims. In fact, § 101.13(i) allows for the use of quantitative nutrient content claims that allow for statements about the amount or percentage of a nutrient. We also note that under section 403(a) of the FD&C Act, a food is deemed misbranded if its labeling is deemed false or misleading in any particular. As such, we would look at any calorie comparison claims on a case-by-case basis to determine if they were false or misleading as used in the particular labeling.

G. Technical Amendments

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

Section 101.9(b)(8)(i) does not state how to round the number of servings for products that contain five or more servings when the number of servings falls exactly between two values. To provide clarity to manufacturers whose products have a number of servings that falls exactly between two values and is greater than five, proposed § 101.9(b)(8)(i) would add that ''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.''

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

Section 101.9(b)(8)(iii) states that, for random weight products, a manufacturer may declare ''varied'' for the number of servings per container provided the nutrition information is based on the reference amount expressed in ounces. In addition, the manufacturer may provide the typical number of servings in parenthesis following the ''varied'' statement, e.g., ''varied (about 6 servings).'' We intended that the term ''random weight product'' refer to products such as certain cheeses that are sold as random weights that vary in size, such that the net contents for different packages would vary (56 FR 60394 at 60412). The serving size for this type of product would be declared on the label as the number of ounces closest to the RACC for the product category with an accompanying visual unit of measure (§ 101.9(b)(5)(iii) (e.g., ''1 oz (28 g/1-inch cube) for bulk cheese)).''

We have identified several difficulties with § 101.9(b)(8)(iii) because: (1) There is no clear definition for which specific products are included in the designation of ''random weight products;'' (2) the requirement that nutrition information be based on the RACC expressed in ounces is confusing because, although serving sizes may be declared in ounces under certain occasions, none of the RACCs are expressed in ounces; (3) the ounce declaration is the last option in the hierarchy of household measures for expressing the serving size (§ 101.9(b)(5)(i), (b)(5)(ii), and (b)(5)(iii)); and (4) it would not necessarily be appropriate for all random weight products to list the serving size in ounces. For example, for a random-weight, multi-serving package of cooked shrimp or crabs, it would be more appropriate to declare the serving size as ''____ shrimp (____ g)'' or ''1 crab (____ g),'' and the number of servings would vary depending on the amount of shrimp or number of crabs in the package.

To resolve these difficulties, we propose to amend § 101.9(b)(8)(iii) to: (1) Define ''random-weight products;'' and (2) eliminate 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.''

3. Minor Corrections to General and Product Category Names

We propose 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. The proposed rule would:

- Change the name of the general category ''Egg and Egg Sustitutes'' to ''Egg and Egg Substitutes'' to correct the error in the current spelling;
- Change the general category name ''Miscellaneous Category'' to ''Miscellaneous'' to be consistent with the manner in which the other general category names are titled;
- In the general category of ''Sauces, Dips, Gravies, and Condiments,'' add ''tomato chili sauce'' to the product category name ''Barbeque sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).'' Tomato chili sauce was included in the initial data analysis for this category, but was accidentally omitted from the category name in the codified text of the 1993 serving size rule. The modified product category would help clarify that although hot chili sauce belongs with hot sauces in the ''Minor condiments, e.g., hot sauce . . .'' category, tomato chili belongs in the ''Barbecue sauce, . . . tomato chili sauce . . .'' category;
- Also in the general category of ''Sauces, Dips, Gravies, and Condiments,'' correct an error in the product category name ''Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce.'' The new product category name would be ''Minor condiments, e.g., horseradish, hot sauces, mustards, Worcestershire sauce.'' ''Worcestershire'' should be capitalized

in the category name and is currently listed in lower case;

• In the general category of ''Snacks,'' correct three errors in the product category name ''All varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips,) grain-based snack mixes.'' First, there is a comma listed in the parenthesis as follows ''(fruit chips,)'' that should be listed outside of the parenthesis as follows ''(fruit chips),''. Second, the product category name ''Fruit-based snacks'' should be changed to ''fruit and/or vegetable-based snacks'', since these products can be made from fruits and/or vegetables. Finally, the word ''popcorns'' should be corrected to be written as ''popcorn'';

• In the general category of ''Vegetables,'' clarify the products that are encompassed in the product category ''Pickles, all types'' by renaming the product category to read as ''Pickles and pickled vegetables, all types.'' The current product category of ''Pickles, all types'' includes all types of pickled vegetables. This minor change will clarify this fact and should help manufacturers more easily locate the appropriate product category for these types of products;

• Also in the general category of ''Vegetables,'' clarify that parsley (an example of an herb used for garnish or flavor) can be in fresh or dried form in the product category ''Vegetables primarily used for garnish or flavor, e.g., pimento, parsley.'' The new product category name would be ''Vegetables primarily used for garnish or flavor, (e.g., pimento, parsley, fresh or dried);'' and

• Change the product category ''Toaster pastries—see coffee cakes'' to ''Toaster pastries—see bagels, toaster pastries, muffins (excluding English muffins)'' because we have proposed to move toaster pastries to a new product category labeled ''Bagels, toaster pastries, muffins (excluding English muffins).''

4. Minor Changes to Footnotes

We are aware of several areas of minor confusion in the footnotes to the RACC tables. Therefore, to reduce misunderstanding, we propose the following minor changes to the footnotes:

• As discussed in section I.D.2 in this proposed rule, both the 1991 serving size proposed rule and the 1993 serving size final rule provided an extensive list of products for each product category that manufacturers could use to determine the RACC for their specific product. Because we intend to update the list of products for each product category and make it available as guidance on our Web site, we are proposing to remove footnote 4 from both tables in § 101.12(b). We are also proposing to renumber the footnotes in each table to reflect the removal of footnote 4.

• Footnote 5 in tables 1 and 2 states that ''[t]he label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required.'' Several manufacturers have interpreted this language incorrectly to mean that the label statements are not required. Because label statements do not necessarily have to use the exact wording provided, but must contain a presentation of the serving size, the proposed rule would correct footnote 5 (proposed footnote 4) to state that label statements are meant to provide examples of serving size statements that may be used on the label, but that the specific wording may be changed as appropriate for individual products.

• Footnote 11 in Table 2 refers to products that are packed or canned in liquid where the RACC refers to the drained solids. The footnote is included as part of the declaration for ''Fruits for garnish or flavor, e.g., maraschino cherries.[11] '' The footnote was inadvertently omitted from the declaration for the current product category ''Vegetables primarily used for garnish or flavor, e.g., pimento, parsley,'' and the proposed rule would add the footnote (proposed Footnote 10) as a superscript to the word ''pimento.''

• Footnote 13 in Table 2 refers the reader to a **Federal Register** document for label statements for serving sizes for raw fruit, vegetables, and fish. Because it is more appropriate to direct the reader to the appendices of the Code of Federal Regulations, we are proposing to amend footnote 13 (proposed footnote 12) to refer the reader to the appendices of the Code of Federal Regulations.

5. Minor Changes to Table 1 in 21 CFR 101.12(b)

• 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 Children 1 through 3 years of age.''

• Change the product category name ''Dinners, stews or soups for toddlers, ready-to-serve'' to ''Dinners, stews or soups for young children, ready-to-serve.''

• Change the product category name ''Fruits for toddlers, ready-to-serve'' to ''Fruits for young children, ready-to-serve.''

• Change the product category name ''Vegetables for toddlers, ready-to-serve'' to ''Vegetables for young children, ready-to-serve.''

6. Minor Changes to Table 2 in 21 CFR 101.12(b)

• Add ''____ pieces (____ g)'' to the label statement for the ''Fruits for garnish or flavor, e.g., maraschino cherries'' to provide for other fruits besides cherries that can be used as a garnish or for flavor.

• Amend the RACC for the ''French fries, hash browns, skins or pancakes'' product category to: ''70 g prepared; 85 g for frozen unprepared French fries''. This amendment is necessary to capitalize the ''f'' in ''french fries.''

• Amend the product category name ''Bean cake (tofu), tempeh'' to ''Tofu, tempeh.''

7. Reference Amounts for Products That Require Further Preparation

Section 101.12(c)(2) states that: ''For products where the entire contents of the package is used to prepare one large discrete unit usually divided for consumption, the reference amount for the unprepared product shall be the amount of the unprepared product required to make the fraction of the large discrete unit closest to the reference amount for the prepared product as established in paragraph (b) of this section.''

This provision allows the RACC to vary based on how the product is packaged. Although the serving size routinely varies depending upon the size of the product and how the product is packaged, the RACC, which is the basis for claims, should not vary. Therefore, the proposed rule would 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. Proposed § 101.12(c) would state that 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. The serving size would remain the same as described in § 101.9(b)(2)(ii).

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. For combined products not in discrete units (e.g., peanut butter and jelly), the reference amount for the combined product is the reference amount for the ingredient that is represented as the main food (e.g., peanut butter) plus a proportioned amount of all minor ingredients of foods (e.g., jelly) (§ 101.12(f)(1)). For combined products where the main ingredient is in discrete units (e.g., pancakes and syrup, cake packaged together with frosting), the reference amount for the combined product is either the number of small discrete units (e.g., pancakes) or the fraction of the large discrete unit (e.g., cake) that is represented as the main ingredient that is closest to the reference amount for that ingredient plus proportioned amounts of all minor ingredients (e.g., syrup, frosting) (§ 101.12(f)(2)).

Although the serving size for this type of product varies depending on the size of the product or how the product is packaged, the RACC, which is the basis for claims, should not vary. Section 101.12(f) allows the RACCs to vary based on the size of the discrete units. For example, for combined products with the main ingredient in discrete units (e.g., pancakes packaged with syrup where pancakes are the main ingredient), the current regulation requires that the RACC for the combined product be based on the weight of the discrete units (e.g., the weight of the pancakes) which varies, rather than on the reference amount for pancakes, which does not vary.

Therefore, the proposed rule would change the definition of the RACC for this type of product in proposed § 101.12(f) so that it will not affect the serving size declaration on the label. The proposed rule would state that the reference amount for the combined products 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, cakes) plus proportioned amounts of all minor ingredients. The serving size would remain the number of discrete units (e.g., pancakes) or the fraction of a large discrete unit (e.g., cake) plus the proportioned minor ingredients closest to the RACC of the combined product.

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 where there is no appropriate reference amount. The current language in § 101.9(h)(3)(ii) states that 8 fluid ounces may be used as the standard serving size for beverage varieties or assortments in gift packages. We are proposing conforming amendments to this section to state that 12 fluid ounces 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 fluid ounces. This change is consistent with the changes to the RACCs discussed in section II.D.2 of this rule. We are proposing to change the RACCs for the ''Carbonated and noncarbonated beverages, wine coolers, water'' and ''Coffee or tea flavored and sweetened'' product categories to 360 mL (or 12 fluid ounces). We are not proposing to change the RACC for milk, fruit juices, nectars, fruit drinks, and vegetable juices, which currently have RACCs of 240 mL or (8 fluid ounces).

III. Proposed Effective and Compliance Dates

We intend 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'' become effective 60 days after the date of the final rule's publication in the **Federal Register** with a compliance date 2 years after the effective date. We recognize that it may take industry 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 their records of product labels and print new labels. A compliance date that is 2 years after the effective date is intended to provide industry time to revise labeling to come into compliance with the new labeling requirements. We invite comment on the proposed compliance date.

IV. 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.

V. Analysis of Impacts

We have examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520).

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 proposed rules on nutrition labeling in the **Federal Register**. We have developed one comprehensive Preliminary Regulatory Impact Analysis (PRIA) (Ref. 63) that presents the benefits and costs of the two proposed nutrition labeling rules taken together; the PRIA is available at *http://www.regulations.gov* (Docket No. FDA–2004–N–0258). The full economic impact analyses of FDA regulations are no longer (as of April 2012) published in the **Federal Register** but are submitted to the docket and are available on this site. We believe that the cumulative impact of the proposed rules on nutrition labeling, taken as a whole, represents a 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 of the proposed rule are small, but not negligible, and as a result we conclude that the proposed rules on nutrition labeling, taken as a whole, would have a significant economic impact. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that we prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''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 $141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. We have determined that the proposed rules on nutrition labeling, taken as a whole, meet this threshold.

The analyses that we have performed to examine the impacts of the proposed rules under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the PRA (see Section V.) are included in the PRIA and are available at *http://www.regulations.gov* (Docket No. FDA–2004–N–0258). We invite comments on the PRIA.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the PRA. A description of these provisions is given in the PRIA available at *http://www.regulations.gov* (Docket No. FDA–2004–N–0258) with an estimate of the annual third-party disclosure burden. Included in the burden 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.

We invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the 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 Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments.''

In compliance with the PRA, we have submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VII. Federalism

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

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

The express preemption provision of section 403A(a) of the FD&C Act does not preempt any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food (section 6(c)(2) of the Nutrition Labeling and Education Act of 1990, Public Law 101–535, 104 Stat. 2353, 2364 (1990)).

If this proposed rule is made final, the final rule would create requirements that fall within the scope of section 403A(a) of the FD&C Act.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IX. References

We have placed the following references on display in FDA's Division of Dockets Management (see **ADDRESSES**). The references may be seen between 9 a.m. and 4 p.m., Monday through Friday. (We have verified all the Web site addresses in the References section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

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

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR 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. Section 101.9 is amended as follows:

■ a. Revise paragraph (b)(2)(i)(D);

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

■ c. Revise paragraphs (b)(6), (b)(8)(i), and (b)(8)(iii);

■ d. Add paragraph (b)(12).

■ e. Revise paragraph (h)(3)(ii)

The revisions 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 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 Daily Values for the individual unit, as well as the preexisting columns listing the quantitative amounts and percent Daily Values for a serving that is less than the unit (i.e., the serving size derived from the Reference Amount Customarily Consumed (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. The exemptions in paragraphs (b)(12)(i)(A), (b)(12)(i)(B), and (b)(12)(i)(C) of this section apply to this provision.

* * * * *

(6) A product that is packaged and sold individually and 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.

* * * * *

(8) * * *

(i) The number of servings must be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings must be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term *about* (e.g., about 2 servings, about 3.5 servings). 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.

* * * * *

(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 parenthesis following the ''varied'' statement.

* * * * *

(12)(i) Products that are packaged and sold individually and contain at least 200 percent and up to and including 400 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 container, as well as the preexisting columns listing the quantitative amounts and percent Daily Values for a serving that is less than the entire container (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 container.

(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 bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or bulk products traditionally used for multi-purposes (e.g., eggs, butter, margarine), and multipurpose baking mixes.

(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, or products that are commonly consumed in combination with another food and provide an additional column of nutrition information under paragraph (e) 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 paragraphs (b)(12)(i) and (b)(2)(i)(D) of this section, the claim must be followed by a statement that sets forth the basis on which the claim is made. The statement must express the amount of the nutrient in a serving (e.g., ''good source of calcium'' ''a serving of ____ oz of this product contains ____ mg of calcium'' or for a health claim ''A serving of ____ ounces of this product conforms to such a diet''). However, if the serving size declared on the product label differs from the RACC, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim must be followed by the criteria for the claim as required by § 101.12(g) of this chapter. This statement is not required for products when the nutrient that is the subject of the claim meets the criteria based on the entire container amount or the unit amount, as applicable.

* * * * *

(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, 1 ounce for solid foods, 2 fluid ounces for nonbeverage liquids (e.g., syrups), and 12 fluid ounces for beverages, except that milk and fruit juices, nectars and fruit drinks, which will be based on 8 fluid ounces, may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph. 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. Section 101.12 is amended as follows:

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

■ b. Revise paragraphs (c) and (f)(1), remove paragraph (f)(2), redesignate paragraph (f)(3) as paragraph (f)(2), and 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 CHILDREN 1 THROUGH 3 YEARS OF AGE [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.	7g 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	170g	____ 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).

[1] These values represent the amount of food customarily consumed per eating occasion and were derived primarily 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 Disease Control and Prevention, in the U.S. 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 (i.e., 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).

[4] 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. 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, heavy weight (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.

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3]—Continued

Product category	Reference amount	Label statement [4]
Cakes, medium weight (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, light weight (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.	30 g	____ cup(s) (____ g).
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	55 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).

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3]—Continued

Product category	Reference amount	Label statement [4]
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	1/2 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, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: all types bulk.	1 cup	1 cup (____ g).
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).	½ cup—includes the volume for coatings and wafers.	____ piece(s) (____ g) for individually wrapped or packaged products; ____ cup(s) (____ g) for others.
Sundae	1 cup	1 cup (____ g).
Custards, gelatin, or pudding	½ cup prepared; Amount to make ½ cup prepared when dry.	____ piece(s) (____ g) for distinct unit (e.g., individually packaged products); ½ 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 Whites 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)	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); 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).

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3]—Continued

Product category	Reference amount	Label statement [4]
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 substitutes, and fruit based drink mixers (without alcohol), e.g., drink mixers, fruit flavored powdered drink mixes, 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)	¼ tsp	¼ 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).

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3]—Continued

Product category	Reference amount	Label statement [4]
Spices, herbs (other than dietary supplements)	¼ tsp or 0.5 g if not measurable by teaspoon.	¼ 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 35g 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, sandwiches.	140g, add 55g 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.	30g	____ 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 confectionaries	10 g	piece(s) (____ g).
Hard candies, breath mints	2 g	____ piece(s) (____ g).
Hard candies, roll-type, mini-size in dispenser packages	5 g	____ piece(s) (____ g).

TABLE 2—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY [1] [2] [3]—Continued

Product category	Reference amount	Label statement [4]
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); ⅓ 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., brussel 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	¼ cup	¼ 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 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 (i.e., 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).

[4] The label statements are meant to provide examples of serving size statements that may be used on the label, but that 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).

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

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

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

[8] Label 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.

[9] Animal 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.

[10] If 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).

[11] The 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(b)(j)(11).

[12] 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.

[13] Pizza 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.

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(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: February 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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