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Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry

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

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Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry[1]

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I. Introduction

This guidance is intended for conventional food and dietary supplement manufacturers. It provides questions and answers on topics related to compliance with our final rules issued on May 27, 2016, entitled "Food Labeling: Revision of the Nutrition and Supplement Facts Labels" (81 FR 33742; the "Nutrition Facts label final rule") and "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments" (81 FR 34000; the "serving size final rule") (codified at title 21 of the Code of Federal Regulations, part 101 (21 CFR part 101)). This guidance also discusses labeling of added sugars, as well as formatting for lines (e.g. thickness of lines) and leading (e.g. space between lines) in the examples of graphics used by FDA on the Nutrition Facts label.

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

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

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

II. Background

On May 27, 2016, we published the Nutrition Facts label and the serving size final rules related to the Nutrition and Supplement Facts labels, which amended our labeling regulations for foods to provide updated nutrition information to assist consumers in maintaining healthy dietary practices.

Below is a summary of the combined major provisions of the Nutrition Facts label final rule and serving size final rule.

The final rules revise the Nutrition Facts and Supplement Facts labels by:

- Removing the declaration of "Calories from fat";
- Requiring the declaration of the gram (g) amount of "added sugars" in a serving of a product, establishing a Daily Reference Value (DRV) for added sugars, and requiring the percent Daily Value (DV) declaration for added sugars;
- Changing "Sugars" to "Total Sugars" and requiring that "Includes 'X' g Added Sugars" be indented and declared directly below "Total Sugars";
- Updating the list of vitamins and minerals of public health significance;
- Updating certain reference values used in the declaration of percent DVs of nutrients on the Nutrition Facts and Supplement Facts labels;
- Revising the format of the Nutrition Facts labels to increase the prominence of the declaration of ''Calories";
- Removing the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets;
- Requiring the maintenance of records to support the declarations of certain nutrients under specified circumstances;
- Amending the definition of a single-serving container;
- Requiring dual-column labeling for certain packages;
- Amending several reference amounts customarily consumed that are used by manufacturers to determine their label serving size; and

- Establishing an effective date of July 26, 2016, and a compliance date of January 1, 2020, for manufacturers with more than $10 million in food sales (originally scheduled to be July 26, 2018) and January 1, 2021, for manufacturers with less than $10 million in annual food sales (originally scheduled to be July 26, 2019).[2]

III. Questions and Answers on Compliance Issues

1. Must the updated Nutrition or Supplement Facts label appear on all foods sold by the applicable compliance date?

After publication of the final rule, we included a frequently asked question on our website asking "When must the label be displayed on food packages?" In our response, we stated that the revised labels were to be displayed on food products that are initially introduced into interstate commerce on or after the compliance date, and said we would address the issue further in guidance. We received a number of questions about products at various points in the distribution chain and whether the product would need to bear the new version of the Nutrition or Supplement Facts label. After further consideration, we are providing the following guidance.

Products that are labeled (i.e., when the label is placed on the product) on or after the applicable compliance date must bear a nutrition label that meets our new nutrition labeling requirements in 21 CFR 101.9 and 21 CFR 101.36. Products that are labeled before the applicable compliance date do not need to be in compliance with the new labeling requirements, and therefore, do not need to bear the new nutrition label.

We consider the date the food product was labeled for purposes of determining whether the product must bear a nutrition label that meets the new requirements. We would not consider the location of the food in the distribution chain to determine whether a food product must bear a nutrition label that meets our new nutrition labeling requirements. For example, the food product, whether labeled before or after the compliance date, may be at the manufacturing facility awaiting distribution, at a warehouse awaiting further distribution, in transit to the United States to be offered for import, or on the store shelf of a U.S. retail establishment.

We do not object to the use of a sticker for providing a revised nutrition label that meets our new requirements in 21 CFR 101.9 and 21 CFR 101.36 before new packaging is printed. The sticker label should not cover any other mandatory information and should adhere to the package during normal handling.

[2] On October 2, 2017, FDA issued a proposed rule that would extend the compliance dates to January 1, 2020 (i.e., for manufacturers with more than $10 million in food sales) and January 1, 2021 (i.e., for manufacturers with less than $10 million in food sales) (82 FR 45753). We finalized the changes to the compliance date in the *Federal Register* of May 4, 2018 (83 FR 19619).

2. When determining whether labels need to be in compliance with the new requirements, should the determination as to whether my company has $10 million or more in annual food sales be based on domestic food sales or total food sales, including international sales, and how many years of sales should I consider?

To determine whether a company has $10 million or more in annual food sales, a firm can either take the smallest sales volume from the previous three years (e.g., 2013, 2014, and 2015), or alternately the firm can take the average of the previous three years sales volume. A firm's total (domestic plus international) food sales best reflects the firm's resources and, thus, ability to comply with the final rules by the applicable compliance date.

3. Are there certain approved companies or nutrition databases that manufacturers can use to get the nutrition values for their products?

FDA does not approve nutrition databases. However, the United States Department of Agriculture provides nutrition information for a number of foods, and there are also several commercially available nutrition databases you can use to determine nutrition values for your products.

4. Who is responsible for the accuracy of the Nutrition Facts label on a food product's label? Who is responsible for maintaining the records needed to verify the accuracy of certain nutrient declarations, including where a firm may perform operations that include those of an ingredient supplier, a manufacturer of a finished food sold under their own brand name, and/or a labeler that labels the product under the firm's or another firm's brand name?

The Federal Food, Drug, and Cosmetic Act prohibits a person from introducing or delivering for introduction, or causing the delivery or introduction, into interstate commerce a misbranded food (21 U.S.C. 331(a)). For example, a supplier has responsibility to ensure that the information about the amount of a nutrient in an ingredient it sells to a manufacturer is accurate, where there is no suitable analytical method available that the manufacturer can use to measure the nutrient's quantity. The manufacturer has responsibility for the accuracy of the nutrient declarations on the label of its food and a manufacturer generally would receive information from its supplier about the amount of the nutrient in the ingredient to ensure the accuracy of the nutrient declaration on the finished food. A distributor that purchases a finished food and then labels the product under its own brand name has responsibility for the accuracy of its food label. Such a distributor also generally would receive information from its supplier (the manufacturer) about the amount of the nutrient in the finished food product to ensure the accuracy of the nutrient declaration on the finished food.

Food manufacturers must make and keep records to support certain nutrient declarations on their product labels (21 CFR 101.9(g)(10)). The recordkeeping requirements specified in 21 CFR 101.9(g), are only for foods for which Association of Official Analytical Chemists (AOAC) International or other reliable and appropriate analytical methods are not available (81 FR 33742 at 33775). The manufacturer of a finished food must make and keep records to support nutrient declarations, as required by 21 CFR 101.9(g)(10) and to make the records

available during an inspection. The manufacturer would be expected to have information from its ingredient supplier if an ingredient contains a nutrient added by the supplier for which there is no suitable analytical method available that the manufacturer can use to measure the nutrient's quantity. In such a case, the amount of the nutrient added may be known only to the supplier.

In situations where we inspect a distributor that distributes a product labeled under its own brand name, and that product includes a nutrient for which there is no suitable analytical method available to measure the nutrient's quantity, we intend to ask the distributor to provide information from the manufacturer that supports the nutrient declaration on the distributor's label for product the distributor introduced, or delivered for introduction, into interstate commerce. Without such information, it is not clear how a distributor could ensure its labeled nutrient declarations do not misbrand its product.

5. How does FDA intend to exercise enforcement discretion with respect to mandatory nutrition labeling for bottled water products and coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors that would have been exempt under § 101.9(j)(4) prior to the effective date of the Nutrition Facts label final rule?

FDA intends to exercise enforcement discretion (i.e., we intend to refrain from taking regulatory or compliance actions) against bottled water products and coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors that would have been exempt under § 101.9(j)(4) with respect to mandatory labeling prior to the effective date of the Nutrition Facts label final rule if these products do not meet the new requirements. We intend to engage in future rulemaking to address issues of mandatory nutrition labeling of these products.

IV. Questions and Answers on Added Sugars

1. What is the definition of added sugars?

We defined added sugars in the Nutrition Facts label final rule (81 FR 33742 at 33980) as sugars that are either added during the processing of foods, or are packaged as such. (e.g., a bag of sugar). Added sugars include sugars (free, mono- and disaccharides), sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. Added sugars do not include fruit or vegetable juice concentrated from 100 percent juices sold to consumers, e.g., frozen orange juice concentrate. In addition, added sugars do not include fruit or vegetable juice concentrates used towards the total juice percentage label declaration under § 101.30 or for Brix standardization under § 102.33(g)(2) of this chapter (refers to § 101). We also do not include fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§ 150.140 and 150.160 of this chapter, or the fruit component of fruit spreads as added sugars.

2. How do I determine how much added sugars are in a serving of my product? Is there a formula or calculator that I can use?

The amount of added sugars in a serving of a product can be determined by a number of different methods. It is up to the manufacturer to determine which ingredients provide sugars that meet the definition of added sugars. Manufacturers are in the best position, given their knowledge of their supply chain and production practices, to determine what method is most suitable for determining the added sugars declaration. We do not have a specific formula or calculator that must be used for determining the amount of added sugars in a finished food product.

Generally, the amount of added sugars in a serving of a product can be determined by examining the ingredients used to formulate the product. Some ingredients themselves (e.g., sugar, corn syrup, or honey) meet the definition of "added sugars." Other ingredients may contain sugars that are consistent with our definition of added sugars that must also be taken into consideration when calculating the added sugars declaration (e.g. semi-sweet chocolate chips, sweetened dried fruit, or flavorings). Manufacturers may need to work with their suppliers to determine the amount of free mono- and disaccharides in ingredients used in a food's formulation. Once all sources of sugars that meet our definition of added sugars are determined, the amount of those sugars from each ingredient should be added or calculated based on processing steps for the finished food (e.g., as a result of dilution of a concentrated fruit or vegetable juice or fermentation) to determine the amount of added sugars in a serving of the product containing the ingredients.

3. Do I need to take into consideration sugars from ingredients that are used in formulating my product when determining the added sugars declaration for a serving of my product?

Ingredients containing free mono- and disaccharides that meet our definition of added sugars need to be taken into consideration when calculating the added sugars declaration for a serving of a product (e.g. sugars from cane sugar and concentrated fruit juice added to sweeten an apple sauce). Manufacturers may need to work with ingredient suppliers to determine the amount of added sugars provided by ingredients used in formulating food products.

4. Do the sugars in dried fruits meet the definition of added sugars?

In the Nutrition Facts label final rule, we responded to comments on dried fruits (see response to comment 212, 81 FR 33742 at 33837). We said that dried fruits which have not had any sugar added to them should not be considered to contain added sugars because they are essentially a dehydrated whole fruit and still retain the nutrients and other components of a whole fruit (e.g. diced dried apples). However, if additional sugar is added to a dried fruit, the sugar added to the dried fruit must be declared on the label as added sugars (81 FR 33742 at 33837).

5. Are the sugars used in the production of vinegar added sugars?

In the production of vinegar, naturally occurring sugars are first fermented into alcohol and then a secondary fermentation occurs in which alcohol is converted to vinegar. For most vinegar products, no sugars remain in the final product. Vinegars that do not contain any sugars in the finished food would not need an added sugars declaration. However, we are aware of some vinegars (e.g., balsamic vinegar) that are made using ingredients that are often used as sweeteners in foods, and that are similar to concentrated fruit juices (e.g., grape must). According to the definition of added sugars, sugars found in concentrated fruit and vegetable juices that are in excess of what would be expected in the same volume of 100 percent fruit or vegetable juice of the same type are added sugars. Therefore, fruit juices that are concentrated before or during processing of some vinegars contain sugars that are consistent with our definition of added sugars. To the extent that sugars that meet our definition of added sugars are present in the finished product, the added sugars must be declared on the label and in labeling, as required in our Nutrition Facts label final rule. We understand that the manufacturing of vinegar involves several steps, and manufacturers need to consider the impact of these steps (e.g. potential concentration due to water loss when aged in wooden barrels) on the final added sugars declaration.

6. The definition of added sugars excludes the "fruit component of fruit spreads." What constitutes the "fruit component" of a non-standardized fruit spread?

Please see our response to question 1 above. The fruit component of a non-standardized fruit spread would include whole fruits, pieces of fruit, dried fruit, fruit or vegetable purees (single strength or concentrated), fruit pulps, single strength juices, fruit and vegetable pastes, and fruit and vegetable powders that are not made from fruit or vegetable juices.

7. Do sugars found in fruits and vegetables that have been processed to change the form of the fruit or vegetable (e.g., concentrated fruit and vegetable purees, fruit and vegetable pastes, and fruit and vegetable powders) need to be declared as added sugars on the label?

In the Nutrition Facts label final rule (81 FR 33742 at 33833), we explained that we excluded from the definition of "added sugars" whole fruit, fruit pieces, dried fruit, pulps, and purees because they are nutrient rich and maintain the basic properties of a fruit when added to foods and are not considered to contain added sugars (see response to comment 208, 81 FR 33742 at33835). We also explained that sugars from 100 percent fruit and vegetable juices, and sugars from certain fruit and vegetable juice concentrates used towards the total juice percentage label declaration under certain regulations, fruit juice concentrates used to formulate the fruit component of jellies, jams, and preserves under our standards of identity, and 100 percent juice concentrate sold directly to consumers (e.g. frozen orange juice concentrate) are excluded from the definition of "added sugars."

In the preamble to the Nutrition Facts final rule (81 FR 33742 at 33833 through 33834), we explained that, while foods sweetened with concentrated fruit or vegetable juices can be a part of a healthful diet, the sugars added to the foods by the concentrated fruit or vegetable juice provide additional calories. Over the course of the day, small amounts of calories in sugar-sweetened foods and beverages can add up and make it difficult to balance the amount

of calories expended (81 FR 33742 at 33834). For these reasons, we consider foods sweetened with concentrated fruit or vegetable juices to be sugar-sweetened foods (id).

We also explained that in determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 Dietary Guidelines Advisory Committee (DGAC) report (Ref. 1) (81 FR 33742 at 33835).

We are applying these same guiding principles when determining when the sugars in an ingredient are added sugars. Concentrated fruit and vegetable purees, fruit and vegetable pastes, and some fruit and vegetable powders are essentially whole fruits and vegetables that have been processed to change the physical form of the fruit or vegetable and to remove moisture. They maintain the basic properties of a whole fruit or vegetable, even if the peel and seeds may be removed. Their composition and use is more consistent with that of whole fruits or vegetables, dried fruits or vegetables, pulps and purees than that of concentrated fruit juices, which are commonly used by industry in place of sugars. Therefore, the sugars in concentrated fruit and vegetable purees, fruit and vegetable pastes and some fruit and vegetable powders contribute to the diet the same way that sugars found in whole fruits or vegetables do, and do not have to be declared as added sugars on the label. However, we consider sugars in powders made from fruit and vegetable juices to be the same as those found in concentrated fruit and vegetable juices because such powders are essentially concentrated fruit and vegetable juices that have all moisture removed. Therefore, some or all sugars contributed by a powder made from fruit or vegetable juices must be declared as added sugars on the label as required by the Nutrition Facts label final rule, depending on the degree of reconstitution in the finished food.

The definition of added sugars includes sugars from concentrated fruit and vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type. The definition of added sugars excludes sugars from fruit or vegetable juice concentrated from 100 percent juices sold to consumers. We said, in the preamble of the Nutrition Facts label final rule, that concentrated juice products made from 100 percent juice (e.g., frozen orange juice concentrate) that are sold directly to consumers (e.g. in grocery stores or on the Internet) are typically reconstituted with water by consumers before consumption, and the packaging of such products typically provides directions for reconstituting the concentrated juice to 100 percent juice (81 FR 33742 at 33834). Similarly, powders made from fruit and vegetable juices that are sold to consumers in drink mixes typically provide directions to dilute the product with water before consumption. Therefore, we would consider powdered fruit and vegetable juices made from 100 percent juices which are sold to consumers with instructions to use water to reconstitute the juice to single strength (100 percent) to be the same as non-powdered 100 percent fruit or vegetable juices described in the final rule. Therefore, the sugars in powdered fruit and vegetable juice made from 100 percent juices which are sold to consumers in drink mixes with instructions to use water to reconstitute the juice to single strength do not need to be declared as added sugars on the label.

The determination of the amount of added sugars contributed by a powdered fruit or vegetable juice that is added as an ingredient to a product and that is not reconstituted to

single strength juice during processing (e.g., that is added to a pureed fruit or to a yogurt) would be the same as the determination of the sugars contributed by a liquid or frozen fruit or vegetable juice concentrate. In our response to question 11, we have suggested that when calculating the added sugars declaration for a product containing concentrated fruit or vegetable juice, the total moisture content of the finished product can be considered to go towards reconstitution of the fruit juice concentrate in the formulation. Thus, the total moisture content of a finished product formulated with powdered fruit or vegetable juice concentrates can be considered to contribute towards the dilution of the powdered fruit or vegetable juice. Further, the sugars contributed by the powdered fruit or vegetable juice that are in excess of what would be expected in the same volume of 100 percent fruit or vegetable juice of the same type must be declared as added sugars on the label, as required by our Nutrition Facts label final rule.

8. Can I use Brix values to calculate the added sugars declaration for a product containing juice concentrates?

We use Brix values to calculate the labeled percentage of juice from concentrate found in a juice or juice beverage using the minimum Brix values provided in 21 CFR 101.30. We have determined that single strength (100 percent) juice contains at least the specified minimum Brix for each single strength juice listed in 21 CFR 101.30.

For a juice concentrate, the added sugars are those that are in excess of what would be expected from the same volume of 100 percent juice of the same type. Therefore, to calculate the added sugars in the concentrated juice ingredient, you need to know the amount of sugars in the 100 percent juice (i.e. single strength juice) of the same type. This may be obtained in several ways. For example, if you know the sugar content of the single strength fruit juice before it is concentrated and added to the product, because the amount of sugar from the single strength juice has been determined through chemical analysis, you may use the known sugar content when calculating and determining the added sugars declaration. You also may choose to use the Brix values provided in 21 CFR 101.30 as an estimate of the sugar content of the single strength juice.

We recognize that industry uses the Brix values provided in 21 CFR 101.30(h)(1) when reconstituting juices as the minimum Brix that the 100 percent juice must have to meet. We understand that to account for process variability, industry may reconstitute to a slightly higher Brix to ensure that the 100 percent juice product consistently meet the minimum juice soluble solids requirements of 21 CFR 101.30(h)(1). Based on the information we have available to us, we would expect that the slight overage of juice soluble solids above the minimum Brix value used to account for process variability is small and would be consistent with our Current Good Manufacturing Practices[3] (cGMPs). Therefore, we would not expect such slight overages to be included in the declaration of added sugars. However, if a product is designed to achieve a higher juice soluble solids concentration than what is required by the minimum Brix value for 100% juice (e.g., to increase sweetness) and the excess is above the cGMP variations described above, the amount of sugars that are in excess of what would be expected from the same volume of 100 percent juice of the same type are added sugars, and

[3] https://www.fda.gov/food/guidanceregulation/cgmp/.

must be declared as such as required by our Nutrition Facts label final rule (also see Q&A 11 and 12).

We require that, when a mixture of naturally occurring and added sugars is present in the food, a manufacturer must make and keep written records of the amount of added sugars added to the food during the processing of the food, and if packaged as a separate ingredient, as packaged (whether as part of a package containing one or more ingredients or packaged as a single ingredient) (21 CFR 101.9(g)(10)(iv)). If you use Brix values provided in 21 CFR 101.30 to calculate the amount of added sugars in a product containing juice concentrate, you must document this information in the records regarding the amount of added sugars added to the food during processing (21 CFR 101.9(g)(10)). If you use the amount of sugars present in a single strength juice and/or a juice concentrate, that is determined through chemical analysis or other available information, when calculating the amount of added sugars in a product containing fruit juice concentrate, you must document the source of the information and/or the amount of sugars determined through chemical analysis in the records that you make and keep (21 CFR 101.9(c)(6)(iii)). If a diluted juice concentrate slightly exceeds the amount of sugar that would be found in the same volume of the same type of 100 percent fruit juice, manufacturers should document the overage and consistency with cGMPs in the records that they make and keep.

9. Should the added sugars contribution from concentrated fruit or vegetable juices be determined on a volume basis or on a weight basis?

The amount of added sugars declared on the label must be in grams (21 CFR 101.9(c)(6)(iii)).

The added sugars definition includes sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100 percent fruit or vegetable juice of the same type.

For juice, the serving size is based on volume (e.g., 8 oz. or 240 ml) while the amount of added sugars per serving is based on weight. Therefore, when calculating the weight of added sugars per serving, you may need to consider the densities of both the finished juice product and the single strength juice of the same type.

You may choose to arrive at the gram amount of added sugars in different ways. Please see our responses to questions 11 and 12 for examples of how to calculate the amount of added sugars in products containing concentrated fruit juices on both a volume and weight basis.

10. How should I calculate the amount of added sugars in a fruit or vegetable juice (juice made from a single type of fruit or vegetable) that is reconstituted to have a sugar content above that in a single strength juice where the excess sugar content is above what is consistent with cGMPs (see Q&A 9)?

In the hypothetical example below, we provide three general steps to calculate the amount of added sugars (in grams) for an apple juice product (240 ml serving size) that is reconstituted to have a sugar content above that in a single strength apple juice. The product in this hypothetical example is reconstituted to have juice soluble solids above the minimum Brix

requirement in 21 CFR 101.30 where the excess sugar content is above what is consistent with cGMPs (see Q&A 9). Therefore, all sugars in excess of what would be expected in the same volume of the same type of single strength juice must be declared as added sugars. The apple juice example here uses the Brix value as an estimate for the sugar concentration. This example is provided solely to demonstrate one method of calculating the added sugars content of the product. You can use alternate methods.

Step 1: Obtain the total weight of sugars (in grams) per 240 ml serving size in the final apple juice product.

This amount would be used for the total sugar declaration per 240 ml serving size of your finished apple juice product.

Step 2: Obtain the weight of sugars (in grams) per 240 ml serving size if the apple juice were reconstituted to single strength juice (i.e., the weight of sugar in the theoretical single strength juice of the same type).

There are different ways to obtain this information. For example, you may obtain such information from your juice concentrate supplier. You may look up such information in private or public nutrient databases. You may also choose to experimentally make a single strength apple juice and measure the total amount of sugar per 240 ml serving. In addition, you may use the following method to calculate the amount of sugar per 240 ml serving in a single strength apple juice.

a) Single strength apple juice has a Brix value of 11.5 (21 CFR 101.30). You may use the Brix value as an estimate for the sugar concentration in a single strength apple juice or other information such as data obtained through chemical analysis, information from databases, or reference documents (see response to Q&A 9). Therefore, the sugar concentration in a single strength apple juice is 11.5% (based on weight).

b) Determine the density of single strength apple juice with a Brix value of 11.5. You can either measure the density or look up references that convert Brix values to densities.

c) The amount of sugars in 240 ml serving size of single strength apple juice of the same type = 240 ml x density (g/ml) x 11.5 % (or .115).

Step 3: The weight of added sugars (in grams) is the weight of sugars obtained from step 1 minus that from step 2.

11. How should I calculate the amount of added sugars in a fruit juice blend containing the juices of multiple fruit types that is reconstituted above 100 percent where the excess sugar content is above what is consistent with cGMPs (see Q&A 9)?

If the juice blend is reconstituted such that the amount of sugar in the finished product is equal to or less than what would be expected in the same volume of the same type of single strength juice (e.g., less than 100% juice), the added sugar declaration would be zero.
If the juice blend is reconstituted such that the amount of sugar in the finished product is greater than what would be expected in the same volume of the same type of single strength

juice and beyond the cGMP variations discussed in Q&A 9, the amount of sugar that is in excess of what would be expected in the same volume of the same type of single strength juice must be declared as added sugars on the label.

For a blended juice, the serving size is based on volume (e.g., 8 oz. or 240 ml) while the amount of added sugars per serving is based on weight. Therefore, when calculating the weight of added sugars per serving, you may need to consider the densities of both the finished juice blend product and the single strength juice of the same type (with the same ratios of various juices).

We provide a hypothetical example below of how the amount of added sugars (in grams) in a serving (240 ml) may be calculated for a juice blend containing concentrated fruit juices of multiple fruit types that is reconstituted to have final a sugar content greater than that of a single strength juice of the same type. In this hypothetical example, we assume the excess sugars are not those added by the manufacturer to meet the requirements of 21 CFR 101.30, and thus, all sugars in excess of what would be expected in the same volume of the same type of single strength juice must be declared as added sugars, as required by our Nutrition Facts label final rule (please see Q&A 11). This hypothetical example uses the Brix value (21 CFR 101.30) as an estimate for the sugar concentration, however other information, such as the sugar content determined through chemical analysis, can be used instead of the Brix value. The example is provided solely to demonstrate one method of calculation. You can use alternate methods to calculate the added sugars content.

Hypothetical juice blend example:

A manufacturer produces a fruit juice blend with 10% apple juice concentrate (70 Brix), 10% mango juice concentrate (70 Brix), 20% pear juice concentrate (70 Brix), and 60% water. The formulation is based on weight. The finished product serving size is 240 ml. If your formulation is based on volume, you will need to convert your volume-based formulation to a weight-based formulation and follow the steps below or use an alternative approach.

Hypothetical example: % formulation (based on weight)	% sugar in single strength juice (21 CFR 101.30, use Brix values as estimates)
10% concentrated apple juice (70% sugar)	11.5% sugar
10% concentrated mango juice (70% sugar)	13% sugar
20% concentrated pear juice (70% sugar)	12% sugar
Water (60%)	

The general steps are similar to those described in Q&A 11.

Step 1: Obtain the total weight of sugars (in grams) per 240 ml serving size in the final juice blend.

This amount would be used for the total sugar declaration per 240 ml serving size of your finished juice blend product.

Step 2: Obtain the weight of sugars (in grams) per 240 ml serving size if the juice blend were reconstituted to single strength juice of the same type (i.e., the weight of sugars in the theoretical single strength juice of the same type). The single strength juice of the same type is a juice that contains the same ratios of the apple, mango, and pear juices in our hypothetical example.

There are different ways to obtain this information. For example, you can make a single strength juice blend with the same ratios of the three juices and measure the amount of total sugars per 240 ml serving size.

You can also calculate the sugar weight in the theoretical single strength juice blend of the same type by the following method:

a) Calculate the ratios of the three juices in your formulation based on weight.

To obtain the weight-based ratios of the three juices in this hypothetical juice blend example, you need to first determine the weight-based concentration factors for the three types of juice. The weight-based concentration factor is the ratio of the Brix values between the concentrate and the single strength juice. For example, the weight-based concentration factor for the apple juice in the hypothetical example is 70 / 11.5 = 6.087. Using a similar calculation, the weight based concentration factor for the mango juice is 5.385 and the weight based concentration factor for the pear juice is 5.833.

Because the hypothetical juice blend formulation has 10% apple juice concentrate (70 Brix), 10% mango juice concentrate (70 Brix), and 20% pear juice concentrate (70 Brix), the theoretical single strength juice blend of the same type would have the following ratios of single strength apple juice, single mango juice, and single pear juice:

Percentage apple juice concentrate in the formulation × apple juice concentration factor; percentage mango juice concentrate in the formulation × mango juice concentration factor; percentage pear juice concentrate in the formulation × pear juice concentration factor

Or

10% × 6.087; 10% × 5.385; 20% × 5.833

Or

0.6087; 0.5385; 1.167

The above ratios for the three types of juice can be converted to percentage-based ratios with the sum of the ratios being 100%. The sum of the ratios is 100% because all of the sugars in the juice blend are from the three types of juices.

Therefore:

Single apple juice: single strength mango juice: single strength pear juice =

{[0.6087 / (0.6087 + 0.5385 + 1.167)] x 100%}:
{[0.5385 / (0.6087 + 0.5385 + 1.167)] x 100%}:
{[1.167 / (0.6087 + 0.5385 + 1.167)] x 100%}

Or

26.30%: 23.27%: 50.42%

b) Calculate the theoretical Brix value of the single strength juice blend of the same type juice with the same ratios of the three juices.

The theoretical Brix value of the juice blend is the sum of the multiplication products of the Brix value and the percentage contribution (the ratio percentage from step 2a) for each type of juice.

(Single strength apple juice Brix × percentage contribution of single strength apple juice) + (single strength mango juice Brix × percentage contribution of single strength mango juice) + (single strength pear juice Brix × percentage contribution of single pear juice) = theoretical Brix value of the hypothetical juice blend.

11.5% × 26.31% + 13% × 23.27% + 12% × 50.42% = 12.10%.

c) Determine the density of single strength juice blend with a Brix value of 12.10. You can either experimentally measure the density or look up references that convert Brix values to densities.

d) The amount of sugars in 240 ml serving size of the theoretical single strength juice blend of the same type with the same ratios of the three types of juice = 240 ml × density (g/ml) × 12.10 %.

Step 3: The weight of added sugars (in grams) is the weight of sugars obtained from step 1 minus that from step 2.

12. How do I calculate the amount of added sugars from a fruit or vegetable juice ingredient when the fruit or vegetable juice ingredient is diluted by other water-containing ingredients in a formulation or concentrated due to water loss during processing (e.g., drying or baking)?

The amount of added sugars is based on the finished product composition. Juice (fruit or vegetable) ingredients are unique in that the amount of added sugars from the juice ingredient depends on whether the juice ingredient is concentrated, and thus, contains sugar in excess of what would be expected from the same volume of 100 percent juice of the same type.

We realize that food formulation is complex and manufacturers can use different ingredients or alternative formulas to achieve the same finished product composition. For example, you may use 100% fruit juice and dry sugar in a baking application. You also may have an alternative formulation that uses concentrated fruit juice and liquid syrup to achieve the same product composition.

When water or other wet ingredients containing water (e.g. milk, syrup, egg, diluted wines and cider with less than 7 percent alcohol by volume, etc.) are added to a formulation containing concentrated juice and other ingredients during processing, the amount of moisture that goes towards reconstituting the juice or towards wetting or reconstituting other ingredients is not known. Furthermore, if the water added during formulation is divided among the ingredients when determining the amount of reconstitution or wetting that has occurred, different formulations of the same finished food could have different calculated added sugar amounts. Therefore, we considered an approach that we believe would provide a reasonable estimate of the added sugars content of a multi-ingredient product that includes concentrated fruit juice as an ingredient (e.g. a bakery product, marinade, or diluted wines and cider with less than 7 percent alcohol by volume). When concentrated juices are used in the formulation, we believe that it is practical to use all of the moisture in the formulation towards reconstitution of the concentrated juice when calculating the amount of added sugars in a serving of the product.

It is also possible that the initial juice ingredient in the formulation (either diluted, 100%, or concentrated) is further concentrated during processing due to loss of water (e.g., during drying or baking). Because the amount of added sugars is based on the finished product composition, you should account for the loss of water during processing to reflect the concentration of the juice ingredient after processing. Considering the complexity of food formulation and processing, we believe it is also appropriate to use the moisture content of the finished product towards reconstitution of the juice soluble solids when the product is subject to water loss during processing. This approach is consistent with our approach for the use of all of the moisture in the formulation towards reconstitution of concentrated juices when calculating the added sugars content of an ingredient.

The following general approach can be used to calculate the amount of added sugars from a juice ingredient in a multi-ingredient formulation. This general approach applies when there is either dilution or concentration during manufacturing.

Step 1: Determine the amount of total sugars contributed by the juice ingredient.

Step 2: Determine the water content (i.e., the moisture content) of the finished product.

Step 3: Determine the sugar concentration of the juice ingredient with the assumption that all of the water in the finished product can be used to reconstitute the juice ingredient.

Step 4: Compare this sugar concentration of juice ingredient with that of the theoretical single strength juice of the same type.

(a) If the sugar concentration is less than, or the same as, the sugar concentration in the theoretical single strength juice of the same type, the amount of added sugars from the juice ingredient is zero.

(b) If the sugar concentration is greater than the sugar concentration in the theoretical single strength juice of the same type, you may use the method described in Q&A 11 or other alternative methods to determine the amount of added sugars from the juice ingredient.

Step 5: The amount of total added sugar per serving is the amount of added sugars from the juice ingredient determined from step 4(b) plus added sugars from other ingredients (e.g., cane sugar), if any, in the formulation.

If you use multiple juice ingredients in your formulation, you may follow the same general steps above except that in step 4(b) you would need to use the method described in Q&A 12 or other alternative methods to determine the amount of added sugars from the multiple juice ingredients.

To demonstrate the general approach described above, we provide two hypothetical examples below. In these hypothetical examples, we use the Brix value as an estimate for the sugar concentration.

Hypothetical example 1:

A product formulation contains a single juice ingredient (5% apple juice at 70 Brix value). The finished product has a serving size of 250 gm and a moisture content of 50%.

Step 1: The amount of total sugars in the juice ingredient = weight per serving × percentage apple juice concentrate × % sugar in apple juice concentrate = 250 g × 5% × 70% = 8.75 g.

Step 2: The water content or the moisture content of the finished product = weight per serving × moisture content = 250 g × 50% = 125 g.

Step 3: The apple juice sugar concentration if we assume all of the water in the finished product is used to reconstitute the apple juice = 8.75 g / 125 g = 7%.

Because 7% is less than the sugar concentration in the theoretical single strength apple juice (11.5 Brix value), the added sugar from the apple juice ingredient in this hypothetical example is zero even though the starting ingredient is a concentrated apple juice.

Hypothetical example 2 (with drying step where water is removed):

A product formulation contains a single juice ingredient (20% single strength apple juice at 11.5 Brix) in the wet formulation (prior to drying). The blended wet formulation has a water content of 50% (i.e., a solids content of 50%). The product goes through a drying step. The finished product has a water content of 10% (i.e., a solids content of 90%) and a serving size of 40 g.

Step 1: The amount of total sugars contributed by the apple juice ingredient per serving.

Because there is water loss during manufacturing, in this method we calculate the amount of wet formulation needed to yield 40 g serving size finished product.

- Solids content in the finished product g = 40 x 90% = 36 g.
- Because the solids prior to drying is 50% (moisture = 50%), the starting wet formulation prior to drying that yielded the 40 g serving size finished product is 72 g (36 g / 50%).
- The amount of total sugar contributed by the apple juice ingredient per serving (based on wet formulation weight percentage) = 72 g × 20% × 11.5% = 1.656 g.

Step 2: The water content of the finished product = weight per serving × moisture content = 40 g × 10% = 4 g.

Step 3: The apple juice sugar concentration if we assume all of the water in the finished product is used to reconstitute the apple juice = (1.656 g/ 4 g) × 100 = 41.4%.

- Since 41.4% is greater than the sugar concentration in the theoretical single strength apple juice (11.5 Brix value), you would need to calculate the amount of sugars from the apple juice ingredient (41.4% sugar) that are in excess of what would be expected from the same volume of 100 percent apple (11.5% sugar). Please note that, in this hypothetical example, even though the starting juice is a single strength juice, because of the concentration during processing, the amount of added sugars from the apple juice is not zero. You may use the method described in Q&A 11 or other alternative methods to determine the amount of added sugars from the juice ingredient.

13. The regulation says in 21 CFR 101.9(c)(6)(iii) that added sugars are a "statement of the number of grams of added sugars in a serving, except that label declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content." What does FDA consider to be a "sweetener?" Do sweeteners include sugar alcohols and other low-calorie sweeteners?

We have used the term "sweetener" to refer to ingredients that provide sweetness to a food regardless of whether they provide calories (43 FR 43248, September 22, 1978; 56 FR 60437 to 60438, November 27, 1991; and 58 FR 2326 to 2327, January 6, 1993). We have not changed our approach to the use of this term. Therefore, we consider both caloric and non-caloric sweeteners, including sugar alcohols, to be sweeteners for the purposes of this regulation.

14. Some ingredients contain mono- and disaccharides (DP1 and DP2 (one and two degrees of polymerization)) that are created through processes such as hydrolysis. Do the mono- and disaccharide portions of ingredients that are created through hydrolysis need to be declared as added sugars on the label?

In the preamble to the Nutrition Facts label final rule (81 FR 33742 at 33832), we said that, other than sugar syrup types of products where the sugars are specifically and purposely produced via hydrolysis, we do not have information suggesting that sugars produced through incidental hydrolysis of complex carbohydrates results in significant increase in the sugar content of foods. We did not receive any comments or other information suggesting that these sugars should be captured under the added sugars declaration, and we did not include sugars produced through incidental hydrolysis in our definition of added sugars (id.). Therefore, such sugars would not be declared as added sugars on the label. We also explained that if a manufacturer purposely employs a hydrolysis step as part of a food manufacturing process to increase the sugar content of a food product (e.g. enzymatic hydrolysis of corn starch to make corn syrup in the same facility as part of the cookie-making process), we would consider the sugar generated from the hydrolysis step to be added sugars, since hydrolysis was purposely used by the manufacturer to increase the sugar content of the product (id.).

In the preamble to the Nutrition Facts label final rule (81 FR 33742 at 33835), we also said that, in determining which sugars should be included in the definition of added sugars, we have considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of empty calories, as discussed in the 2015 Dietary Guidelines Advisory Committee Report (2015 DGAC Report).

Manufacturers may purposely employ methods, such as hydrolysis, for a number of reasons, some of which result in an ingredient containing mono- and disaccharides with DP1 and DP2. Ingredients such as maltodextrin and corn syrup solids are hydrolyzed to achieve various degrees of dextrose equivalence (DE). The higher the DE, the lower the degree of polymerization, and the sweeter the ingredient becomes. Maltodextrins (21 CFR 184.1444) are ingredients with a DE less than 20, and corn syrup (21 CFR 168.120, 168.121, and 184.1865) are ingredients with a DE of 20 or higher. Depending on the manufacturing process, different maltodextrin and corn syrup will have different DE and different amounts of mono- and disaccharides. Although maltodextrins are not used primarily for sweetening purposes, depending on the DE, some can contain 8-9% mono and disaccharides and can contribute to sweetness. We also understand that the hydrolysis process to manufacture maltodextrin and corn syrup are controlled so that the desired DE can be consistently achieved. This indicates that some maltodextrins and corn syrup solids are manufactured purposely to contain certain levels of mono- and disaccharides. Information that is publicly available (e.g., online product specification sheets and reference materials) indicates that manufacturers have knowledge of the level of mono- and disaccharides created during the processing of ingredients through controlled hydrolysis.

Maltodextrins, corn syrups, and other ingredients with mono-and disaccharides that are created through controlled hydrolysis are widely used by manufacturers and are present in many different types of food products (47 FR 36443 at 36444, September 20, 1982). The sugars contributed by these ingredients are consistent with the concept of empty calories as

described in the 2015 DGAC Report because they supply sugars and calories to the diet when they are added as an ingredient to foods. We explained in the Nutrition Facts label final rule that small amounts of added sugars that are contributed to the diet by a wide variety of foods can add up over the course of the day and can make it difficult for an individual to eat sufficient amounts of foods from the basic food groups to meet nutrient needs without exceeding the amount of calories they need in a day for weight maintenance (81 FR 33742 at 33759). As such, when an ingredient containing mono- and disaccharides that are created through controlled hydrolysis (e.g. maltodextrin or corn syrup) is added to a food during processing, those mono- and disaccharides contributed by the ingredient need to be declared as added sugars on the label (21 CFR 101.9(c)(9)(iii).

15. Does the sugar created through enzymatic hydrolysis of lactose in low-lactose dairy products need to be declared as added sugars?

We received several comments to the Revision of the Nutrition and Supplement Facts Labels proposed rule related to lactose in dairy ingredients, which are summarized in Comment 209 of the Revision of the Nutrition and Supplement Facts labels final rule (the final rule) (81 FR 33742 at 33835). The sugars in dairy ingredients, except lactose as defined in 21 CFR 168.122, are not included in the definition of added sugars. Moreover, lactose that meets our standard of identity is an added sugar.

Lactose, as a sugar in a dairy product, is a disaccharide that is captured on the Nutrition Facts label under the Total Sugars declaration. However, lactose that meets the definition in 21 CFR 168.122 is captured on the Nutrition Facts label under both the Added Sugars and Total Sugars declarations. We are aware that the enzyme lactase is used by industry to hydrolyze lactose present in dairy products for the purposes of reducing the lactose content in low-lactose dairy products. The hydrolysis of lactose results in the monosaccharides glucose and galactose. Regardless of whether hydrolysis of lactose, present in dairy products or in dairy ingredients by lactase is being utilized to reduce lactose or to increase the sweetness of the product, hydrolysis of lactose under such circumstances does not result in an increase in sugars that would affect the Total Sugars declaration. Moreover, to the extent lactose that meets our standard of identity in 21 CFR 168.122 is subject to hydrolysis, the Added Sugars declaration would be the same before and after the hydrolysis of such a lactose ingredient using lactase. Since the hydrolysis of lactose found in dairy products (e.g. milk) and dairy ingredients (e.g. stabilizers and texturizers), and the hydrolysis of lactose that meets our standard of identity, do not result in an increase in the Total Sugars declaration, the hydrolysis process also does not result in an increase in the caloric content of the food. Thus, the sugars created through enzymatic hydrolysis of lactose, whether present as a component of a dairy product, a dairy ingredient, or contributed by the addition of lactose that meets the definition in 21 CFR 168.122, do not change the declarations for Total Sugars or Added Sugars for the product.

16. If sugars are added to a food that already contains inherent sugars (e.g. yogurt), does that make "added sugars" a Class I nutrient for purposes of compliance under 21 CFR 101.9(g)? If so, does that mean that the composite must be formulated to be at least equal to the value for the added nutrient (added sugars) declared on the label per 21 CFR 101.9(g)(4)(i), or is 21 CFR 101.9(g)(5) allowing up to 20% in excess of the value declared applicable?

Added sugars would be a nutrient in a fortified or fabricated food (21 CFR 101.9(g)(3)(i)). Added sugars is not a nutrient listed in 21 CFR 101.9(g)(4)(i). The nutrients listed in this regulation include: vitamins, minerals, protein, and dietary fiber.

When a food contains sugars that are endogenous and not exogenous sugars, the nutrient content of the composite for "Total Sugars" and "Added Sugars" would be subject to 21 CFR 101.9(g)(5). Section 101.9(g)(5) requires that the nutrient content of the composite be no greater than 20 percent in excess of the value for that nutrient declared on the label and states that no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

However, because there are no generally recognized analytical methods available to quantify added sugars in a food when the food contains sugars that do and do not meet our definition of added sugars, the parenthetical after "added sugars" in § 101.9(g)(5) states that, "when the only source of sugars in the food is added sugars." The parenthetical is intended to clarify that the requirement in § 101.9(g)(5) for the added sugars declaration would only apply when there is an analytical method available to quantify the added sugars. When a food contains a combination of sugars that do and do not meet our definition of added sugars, we would verify the declaration of added sugars in a food using the records required by § 101.9(g)(10) and (11).

With respect to the total sugars declaration, § 101.9(g)(5) would apply whether the food contains only added sugars, only sugars that do not meet our definition of added sugars, or a combination of these sugars in a food because there would be an analytical method to quantify "Total Sugars" under any of these circumstances.

A food that already contains some endogenous sugar and additional added sugars, either directly or as a component in an ingredient, such as sweetened fruit added to yogurt, would be misbranded if the actual "Total Sugars" amount is greater than 20 percent in excess of the value for that nutrient declared on the label, or the records requirements for "Added Sugars" are not met (see § 101.9(g)(11)).

17. Do sugars present in a sweet fermented beverage after fermentation need to be declared as total or added sugars on the label?

If the fermented beverage contains only sugars that meet our definition of added sugars (e.g. table sugar), then the amount of sugars present in a serving of the product after fermentation must be declared as both total and added sugars (21 CFR 101.9(c)(6)(iii)).

If the fermented beverage contains both sugars that do and do not meet our definition of added sugars, you may determine the amount of total sugars in the finished food analytically. You have the following options related to the added sugars declaration:

- Determine a reasonable approximation of the amount of added sugars in the finished product and make and keep records of all relevant scientific data and information you relied upon that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation; or

- Declare the amount of added sugars added prior to fermentation and make and keep records to verify the amount (21 CFR 101.9(g)). The amount of added sugars declared should not exceed the amount of total sugars on the label; or

- If you have no way to determine a reasonable approximation of the amount of added sugars in the finished food, but have reason to believe that a significant reduction of added sugars took place during fermentation, you may submit a petition, under 21 CFR 10.30, to request an alternative means of compliance. The petition should provide scientific data or other information for why the amount of added sugars in a serving of the product is likely to be significantly reduced compared to the amount added prior to fermentation. A significant reduction would be where reduction in added sugars after fermentation may be significant enough to impact the label declaration for added sugars by an amount that exceeds the reasonable deficiency acceptable within good manufacturing practice under § 101.9(g)(6). In addition, the scientific data or other information should include the reason why you are unable to determine a reasonable approximation of the amount of added sugars in a serving of the finished product and a description of the process that you used to come to that conclusion.

18. Ingredients made primarily from sugar and created through non-enzymatic browning are added to some products for coloring and flavoring purposes (e.g. caramel color). After non-enzymatic browning occurs, the sugar is reduced in the ingredient. In such a case, how much sugar must be declared as added sugars on the label?

If the remaining amount of the sugar contributed by an ingredient that undergoes non-enzymatic browning is detectable by testing in the finished product, you may declare that amount of sugar that is detectible by analytical testing in the finished product as the added sugars declaration. When such an ingredient is added to a product that contains other sugars that do not meet the definition of added sugars, you must make and keep records, which should include records of the results of the analytical testing that is used to demonstrate the amount of added sugars contributed by the ingredient in the finished product after non-enzymatic browning occurs, and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation (21 CFR 101.9(g)(10)(v)(A)).

19. If sugar is added for fermentation during the leavening process of a baked good and some of the sugars are consumed by yeast, should the reduction in the amount of sugars be accounted for the declaration of added sugars?

As described in our response to question 18, you may declare the amount of added sugars in the food after fermentation. If you do so, you must make and keep records of all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after fermentation and a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food, provided the data and information used is specific to the type of food that is subject to non-enzymatic browning and/or fermentation (21 CFR 101.9(g)(10)(v)(A)).

20. There is a chance that added sugars content prior to non-enzymatic browning and/or fermentation may be higher than the total sugars content of the finished food determined through chemical analysis. How do I approximate the added sugars value in this case?

The added sugars declaration should not exceed the total sugars declaration. In a case where sugars added prior to or during processing are reduced through non-enzymatic browning and/or fermentation, and the manufacturer chooses to declare the amount of sugars added prior to non-enzymatic browning and/or fermentation, the added sugars declaration could conceivably exceed the amount of total sugars determined through chemical analysis. In such a case, you should declare the same amount for added sugars as the amount of total sugars obtained through analytical testing for a serving of the food.

V. Question and Answer on Format Issues

1. What are the specifications for thickness of lines and leading (i.e., space between lines) on the Nutrition Facts label?

Our regulations, at 21 CFR 101.9(d)(1)(ii)(C) and (d)(1)(v) establish certain format requirements with respect to leading and the use of hairline rules.

Additionally, Appendix B to Part 101 in Title 21 provides examples of graphic enhancements (i.e., illustrations) that FDA uses. For more examples of graphic enhancements that FDA uses, please see our webpage at: https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/UCM513883.pdf.

VI. Question and Answer on the Declaration of Quantitative Amounts of Vitamins and Minerals

1. What are the requirements (e.g. for rounding) for the declaration of quantitative amounts of vitamins and minerals declared on the Nutrition and Supplement Facts labels? What does "levels of significance" mean in this context?

We require, under 21 CFR 101.9(c)(8)(iii), that the quantitative amounts of vitamins and minerals, excluding sodium, be the amount of the vitamin or mineral included in a serving of the product using the units of measurement and the levels of significance given in 21 CFR 101.9(c)(8)(iv) (which refers to the Reference Daily Intakes (RDI) table). However, zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams, but the quantitative amount may be declared in tenths of a milligram). This is consistent with the requirements for the declaration of quantitative amounts of vitamins and minerals on the Supplement Facts label (see 21 CFR 101.36(b)(2)(ii)(B)).

In addition, regarding conventional foods, quantitative amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared on the Nutrition Facts label. However, they may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)" or "Contains <2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, if vitamin D, calcium, iron or potassium is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of ___ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values (21 CFR 101.9(c)(8)(iii)).

Regarding dietary supplements, vitamin D, calcium, iron, and potassium must be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with 21 CFR 101.9(c). (21 CFR 101.36(b)(2)(i)).

As for the phrase "levels of significance," as used in 21 CFR 101.9(c)(8)(iii) and 101.36(b)(2)(ii)(B) and whether the phrase refers to statistical testing of hypotheses or mathematical concepts related to the degree of accuracy starting with the first nonzero digit, the phrase "levels of significance" refers to the degree of accuracy when rounding nutrients for purposes of declaring quantitative amounts of vitamins and minerals on the label.

Our regulations, at 21 CFR 101.9(c), provide specific rounding requirements for nutrients such as sodium. Before we issued the Nutrition Facts label final rule, sodium and potassium content was to be expressed as zero when the serving contained less than 5 milligrams (mg), to the nearest 5 mg increment when the serving contained less than or equal to 140 mg, and to the nearest 10 mg increment when the serving contained more than 140 mg. The Nutrition

Facts label final rule amended 21 CFR 101.9(c)(5) to replace the requirements for the labeling of potassium with those of fluoride and amended 21 CFR 101.9(c)(8)(iv) to establish an RDI for potassium and add it to the list of vitamins and minerals with RDIs. The requirements for declaring the quantitative amount of potassium are now the same as those for other vitamins and minerals with RDIs.

The RDIs for some vitamins and minerals are small numerical values (e.g., copper 0.9 mg). Nutrients with an RDI of less than 5 would not be able to be declared on the Supplement Facts label if they contain less than 2 percent of the RDI (e.g. 2 percent of the RDI for copper is 0.018 mg) and the amount is declared to the nearest mg or microgram (mcg) (e.g. if the amount of copper in a serving of the product is 0.017, but is rounded to zero). The vitamins and minerals with an RDI of less than 5 mg or mcg are thiamin, riboflavin, vitamin B_6, vitamin B_{12}, copper, and manganese. With respect to the declared quantitative amounts of these vitamins and minerals, we consider it appropriate for manufacturers to declare the quantitative amounts to the nearest hundredth of a mg or mcg per serving, provided that such a level of specificity does not represent a greater level of precision in the amount of the nutrient present than the method of analysis, database, source of the nutrient, and/or calculation used for the declaration can scientifically support.

A vitamin or mineral with an RDI of at least 5 mg or mcg, but less than 50 mg or mcg, would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest tenth of a mg or mcg per serving. The vitamins or minerals with an RDI of at least 5 mg or mcg but less than 50 mg or mcg are iron, vitamin D, vitamin E, niacin, biotin, pantothenic acid, zinc, chromium, and molybdenum. With respect to the declared quantitative amounts of these vitamins and minerals, we consider it appropriate for manufacturers to declare the quantitative amounts to the nearest tenth of a mg or mcg per serving, provided that such a level of specificity does not represent a greater level of precision in the amount of the nutrient present than the method of analysis, database, source of the nutrient, and/or calculation used for the declaration can scientifically support.

A vitamin or mineral with an RDI of at least 50 mg or mcg, but less than 250 mg or mcg, would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest mg or mcg. The vitamins or minerals with an RDI of at least 50 mg or mcg but less than 250 mg or mcg are vitamin C, vitamin K, iodine, and selenium. With respect to the declared quantitative amounts of these vitamins and minerals, we consider it appropriate for manufacturers to declare the quantitative amounts to the nearest mg or mcg per serving, provided that such a level of specificity does not represent a greater level of precision in the amount of the nutrient present than the method of analysis, database, source of the nutrient, and/or calculation used for the declaration can scientifically support.

A vitamin or mineral with an RDI of at least 250 mg or mcg, but less than 500 mg or mcg, would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest 5 mg or mcg. The vitamins and minerals with an RDI of at least 250 mg or mcg, but less than 500 mg or mcg, are folate and

magnesium. With respect to the declared quantitative amounts of these vitamins and minerals, we consider it appropriate for manufacturers to declare the quantitative amounts to the nearest 5 mg or mcg per serving, provided that such a level of specificity does not represent a greater level of precision in the amount of the nutrient present than the method of analysis, database, source of the nutrient, and/or calculation used for the declaration can scientifically support.

A vitamin or mineral with an RDI of 500 mg or mcg or greater would not be declared on the Supplement Facts label if it contains less than 2 percent of the RDI unless the quantitative amount is declared to the nearest 10 mg or mcg. The vitamins or minerals with an RDI of 500 mg or mcg or greater are vitamin A, calcium, phosphorus, chloride, potassium, and choline. With respect to the declared quantitative amounts of these vitamins and minerals, we consider it appropriate for manufacturers to declare the quantitative amounts to the nearest 10 mg or mcg per serving, provided that such a level of specificity does not represent a greater level of precision in the amount of the nutrient present than the method of analysis, database, source of the nutrient, and/or calculation used for the declaration can scientifically support.

Manufacturers may calculate the percent DV for all nutrients other than protein by dividing either the amount of the nutrient declared on the label or the actual amount of the nutrient (i.e., before rounding) to provide for the greatest amount of consistency on the food label (21 CFR 101.9(d)(7)(ii)).

Recommendations for declaration of quantitative amounts of vitamins and minerals on the Nutrition and Supplement Facts labels using RDIs for adults and children ≥ 4 years

Nutrient	Unit of Measure	RDI for Adults and Children ≥ 4 years	Recommended increment
Vitamin A	Micrograms RAE (mcg)	900	Nearest 10 mcg
Vitamin C	Milligrams (mg)	90	Nearest mg
Calcium	Milligrams (mg)	1,300	Nearest 10 mg
Iron	Milligrams (mg)	18	Nearest .1 mg
Vitamin D	Micrograms (mcg)	20	Nearest .1 mcg
Vitamin E	Milligrams (mg)	15	Nearest .1 mg
Vitamin K	Micrograms (mcg)	120	Nearest mcg
Thiamin	Milligrams (mg)	1.2	Nearest .01 mg
Riboflavin	Milligrams (mg)	1.3	Nearest .01 mg
Niacin	Milligrams NE (mg)	16	Nearest .1 mg
Vitamin B_6	Milligrams (mg)	1.7	Nearest .01 mg
Folate	Micrograms DFE (mcg)	400	Nearest 5 mcg
Vitamin B_{12}	Micrograms (mcg)	2.4	Nearest .01 mcg
Biotin	Micrograms (mcg)	30	Nearest .1 mcg
Pantothenic acid	Milligrams (mg)	5	Nearest .1 mg
Phosphorus	Milligrams (mg)	1,250	Nearest 10 mg
Iodine	Micrograms (mcg)	150	Nearest mcg
Magnesium	Milligrams (mg)	420	Nearest 5 mg
Zinc	Milligrams (mg)	11	Nearest .1 mg
Selenium	Micrograms (mcg)	55	Nearest mcg
Copper	Milligrams (mg)	0.9	Nearest .01 mg
Manganese	Milligrams (mg)	2.3	Nearest .01 mg
Chromium	Micrograms (mcg)	35	Nearest .1 mcg
Molybdenum	Micrograms (mcg)	45	Nearest .1 mcg
Chloride	Milligrams (mg)	2,300	Nearest 10 mg
Potassium	Milligrams (mg)	4,700	Nearest 10 mg
Choline	Milligrams (mg)	550	Nearest 10 mg

This table provides recommendations for the declaration of quantitative amounts of vitamins and minerals using only the RDIs that have been established for adults and children 4 years of age and older. Our regulations, at 21 CFR 101.9(c)(8)(iv), provide RDIs for infants through 12 months, children 1 through 3 years, and pregnant and lactating women. The declaration recommendations provided in this guidance can also be applied to the RDIs for these subpopulations.

VII. References

U.S. Department of Agriculture and U.S. Department of Health and Human Services. "Scientific Report of the 2015 Dietary Guidelines Advisory Committee," Advisory Report to the Secretary of Health and Human Services and the Secretary of Agriculture. Washington, D.C., 2015. Retrieved from: https://health.gov/dietaryguidelines/2015-scientific-report/PDFs/Scientific-Report-of-the-2015-Dietary-Guidelines-Advisory-Committee.pdf