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Regulatory Alert: FDA Issues Draft Guidance on Nutrition Labeling and RACCs

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On January 4, 2017, the U.S. Food and Drug Administration (FDA) issued Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals, which provides questions and answers on topics related to compliance with the FDA final rule: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels."[1] On the same day the Agency also issued Draft Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category.

FDA answered questions relating to labeling of added sugars and compliance dates among other things in the Nutrition Labeling Guidance. The Guidance on Reference Amounts Customarily Consumed (RACC) provides helpful examples of the types of specific products that fall within certain product categories.

The final rule revised the Nutrition 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.
- Updating certain reference values used in the declaration of percent DVs.
- 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 reference amounts customarily consumed that are used by manufacturers to determine label serving size.

[1] 81 Fed. Reg. 33742 (May 27, 2016).

- Establishing an effective date of July 26, 2016 and a compliance date of 2 years after the final rule's effective date, except that manufacturers with less than $10 million in annual food sales have a compliance date of 3 years after the final rule's effective date.

Below is a summary of key questions contained in the Nutrition Labeling guidance and their answers:

1) **Must the updated Nutrition or Supplement Facts label appear on all foods sold by July 26, 2018 (or July 26, 2019 for manufacturers with less than $10 million in annual food sales)?**

A: Products labeled on or after July 26, 2018 (and July 26, 2019 for manufacturers with less than $10 million in annual food sales) must bear a nutrition label that meets the new requirements. Products that are labeled before July 26, 2018 (and July 26, 2019 for manufacturers with less than $10 million in annual food sales) do not need to bear the new nutrition label.

2) **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?**

A: A firm can either take the smallest sales volume from the previous three years or take the average of the previous three years' sales volume. Total sales includes domestic and international sales.

3) **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?**

A: Food manufacturers must make and keep records to support certain nutrient declarations on their product labels. A firm that labels the product, whether the manufacturer or a private labeler must know, for each nutrient declared, the amount of a nutrient in a serving a food to ensure that the label is truthful and accurate and does not misbrand the product. A firm that does not manufacture the product, but that is responsible for labeling the product, is expected to have access to records that are sufficient to verify the nutrient declarations for which records are required in the final rule and to make such records available during an inspection.

4) **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?**

A: Whole fruit, fruit pieces, dried fruit, pulps, and purees maintain the basic properties of a fruit when added to foods, which are not considered to contain added sugars. If a fruit or vegetable is processed so that it no longer contains all the components of the portion of a whole fruit or vegetable that is typically eaten (e.g. the pulp is removed) and the sugars have been concentrated, the sugars must be declared as added sugars

5) **How should the amount of added sugars in a fruit juice blend containing the juices of multiple fruits that have not been reconstituted to 100 percent strength?**

A: If the juice blend is reconstituted such that the sugar concentration is less than what would be expected I the same amount 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 sugar concentration is greater than what would be expected in the same amount of the same type of single-strength juice, the amount of sugar that is in excess of what would be expected in the same amount of the same type of single strength juice must be declared as added sugars on the label. FDA provides examples for calculating the amount of added sugar in the guidance.

6) **Can Brix values be used to calculate the added sugars declaration for a product containing fruit juice concentrates?**

A: Yes. Brix values provided in 21 CFR 101.30 may be used when determining the sugar content of a single strength fruit juice product, which is then used to calculate the added sugars contributed to the product by the concentrated fruit.

7) **The regulation states 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?**

A: FDA has traditionally used the term "sweetener" to refer to ingredients that provide sweetness to a food regardless of whether they provide calories. Therefore, the agency considers both caloric and non-caloric sweeteners, including sugar alcohols, to be sweeteners for purposes of the final rule.

8) **If sugars are added to a food that already contains inherent sugars (e.g. to cranberries, tart cherries, or 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 of 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?

A: 21 CFR 101.9(g) is applicable. A food that already contains some indigenous 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.

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