

Policy Related to Cranberry Products with Added Flavorings: Guidance for Industry

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

August 2019

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This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

I. Introduction

The purpose of this guidance is to advise manufacturers of certain dried cranberry products² with added flavorings of our intent to exercise enforcement discretion until July 1, 2020, for their compliance with the updated labeling requirements set forth in two final rules published in the *Federal Register* of May 27, 2016 entitled, “Food Labeling: Revision of the Nutrition and Supplement Facts Labels” (hereafter referred to as “Nutrition Facts label final rule” (81 FR 33742)) (see 21 CFR 101) 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” (hereafter referred to as the “Serving Size final rule” (81 FR 34000)) (see 21 CFR 101).

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, Nutrition Programs Staff in the Center for Food Safety and Applied Nutrition.

² Certain dried cranberry products are identified as dried cranberry products that are sweetened with added sugars and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars.

II. Background

A. Nutrition Facts Label Final Rule

In the *Federal Register* of May 27, 2016, we issued a final rule updating the Nutrition Facts label for packaged foods to reflect new scientific information (see 81 FR 33742). The Nutrition Facts label final rule includes changes in the individual nutrients that must be declared and also changes some Daily Values (DVs). The science underlying the Nutrition Facts label final rule is also reflected in the *2015-2020 Dietary Guidelines for Americans* (Ref. 1).

The Nutrition Facts label final rule requires that added sugars be included in the Nutrition Facts label and established a DV for added sugars. The Nutrition Facts label final rule defines “added sugars,” in part, to include sugars that are either added during the processing of foods or are packaged as such (21 CFR 101.9(c)(6)(iii)). The term includes free 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. The Nutrition Facts label final rule requires added sugars to be declared on the food label by stating “Includes Xg Added Sugars” indented directly below “Total Sugars” (see 21 CFR 101.9(c)(6)(ii)).

The Nutrition Facts label final rule requires a declaration for added sugars, in part, because excess consumption of added sugars makes it difficult to meet nutrient needs within the calorie limits generally needed to maintain a healthy weight and can lead to an increase in overall caloric intake. Further, healthy dietary patterns characterized, in part, by lower amounts of sugar-sweetened foods and beverages, as compared to less healthy dietary patterns, are associated with a reduced risk of cardiovascular disease. The science underlying the *2015-2020 Dietary Guidelines for Americans* demonstrates that meeting nutrient needs while staying within calorie limits is difficult with more than 10 percent of total daily calories from added sugars (50 grams of added sugars based on a 2,000 calorie diet)(Ref. 1). Based on this science, the Nutrition Facts label final rule establishes a DV for added sugars, 50 grams based on a 2,000 calorie diet for adults and children 4 years of age and older and 25 grams based on a 1,000 calorie diet for children 1 through 3 years of age (21 CFR 101.9(c)(8)(vii)).

In the *Federal Register* of May 4, 2018, we issued a final rule extending the compliance date for the Nutrition Facts Label final rule for manufacturers with \$10 million or more in annual food sales from July 26, 2018, to January 1, 2020; for manufacturers with less than \$10 million in annual food sales, the final rule extends the compliance date from July 26, 2019, to January 1, 2021. (See 83 FR 19619.)

B. Serving Size Final Rule

In the *Federal Register* of May 27, 2016, we issued a final rule pertaining to serving sizes for food (see 81 FR 34000). The final rule amends the definition of a single-serving container, requires dual-column labeling for certain containers, updates the tables of Reference Amounts Customarily Consumed (RACCs), and amends the serving size for breath mints.

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In the *Federal Register* of May 4, 2018, we issued a final rule extending the compliance date for the Serving Size final rule for manufacturers with \$10 million or more in annual food sales from July 26, 2018, to January 1, 2020; for manufacturers with less than \$10 million in annual food sales, the final rule extends the compliance date from July 26, 2019, to January 1, 2021. (see 83 FR 19619).

III. The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Guidance for Industry

In the *Federal Register* of March 2, 2018 (83 FR 8953), we announced the availability of a draft guidance for industry entitled, “The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Draft Guidance for Industry” (hereafter referred to as “the draft guidance”) and asked interested parties to submit comments by May 1, 2018. In the *Federal Register* of April 25, 2018 (83 FR 17961), we extended the comment period to June 15, 2018.

In the draft guidance, we advised food manufacturers of our intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a “†” symbol immediately after the added sugars percent DV information on single ingredient packages and/or containers of pure honey or pure maple syrup and on certain dried cranberry and cranberry juice products that are sweetened with added sugars and that contain total sugars at levels no greater than comparable products³ with endogenous (inherent) sugars, but no added sugars. The “†” symbol would direct consumers to truthful and non-misleading statements on the package outside the Nutrition Facts label that would need to comply with applicable FDA statutory and regulatory requirements. The draft guidance would extend enforcement discretion to include certain cranberry products with added sugars that contain total sugars at levels no greater than comparable products; such cranberry products included dried cranberry products and dried cranberries with added flavorings.

In the *Federal Register* of June 6, 2019 (84 FR 28726), we announced the availability of a final guidance for industry entitled, “The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Guidance for Industry” (hereafter referred to as “the final guidance”)⁴.

The final guidance clarifies the labeling requirements for single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups, which are not required to bear the words, “Includes Xg Added Sugars” but must still include the percent DV for added sugars on their labels. The final guidance also advises food manufacturers of our intent to exercise enforcement discretion with respect to the use of truthful and not misleading statements on single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups.

³ For the purposes of this guidance document, we consider a “comparable product” to be one that is in the same food category (e.g., fruit), that is in the same form (e.g., dried), and that has the same usage (e.g., a snack). For example, we consider unsweetened raisins to be comparable to sweetened dried cranberries.

⁴ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-declaration-added-sugars-honey-maple-syrup-other-single-ingredient-sugars-and?utm_campaign=CFSANCU_Guidance_Added_Sugars_06182019

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Further, the final guidance states our intent to exercise enforcement discretion with respect to the use of a “†” symbol on single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups immediately following the percent DV representing the contribution of added sugars to the diet obtained from a serving of these products. We also intend to exercise such enforcement discretion when the symbol leads the reader to a truthful and not misleading statement within a footnote at the bottom of the Nutrition Facts label that includes a description of the gram amount of sugar added to the diet by one serving of the product and its contribution to the percent DV for added sugars in the diet.

The guidance also states our intent to exercise enforcement discretion with respect to the use in the Nutrition Facts label of the “†” symbol immediately after the added sugars percent DV information that leads consumers to a statement outside of the Nutrition Facts label on certain dried cranberry and cranberry beverage products that are made up of cranberry juice that is sweetened with added sugars and that contain total sugars at levels no greater than comparable products with endogenous (inherent) sugars, but no added sugars.

The final guidance advises manufacturers of single-ingredient packages and/or containers of pure honey, pure maple syrup, and other pure sugars and syrups, as well as certain dried cranberry and cranberry beverage products of our intent to exercise enforcement discretion until July 1, 2021, for complying with the updated labeling requirements in the Nutrition Facts label final rule and the Serving Size final rule.

IV. Discussion

When we published the draft guidance, we extended our enforcement discretion to include certain cranberry products with added sugars that contain total sugars at levels no greater than comparable products. The draft guidance did not expressly discuss cranberry products with added flavorings. However, in the final guidance, we did not extend enforcement discretion to dried cranberries with added flavorings. After we announced the availability of the final guidance, we received correspondence from certain cranberry manufacturers (Ref. 2). The cranberry industry presented us with concerns that manufacturers of dried cranberries with added flavorings have regarding their ability to comply with the Nutrition Facts label final rule and Serving Size final rule by January 1, 2020 and requested that we extend the compliance date for the final rules for dried cranberries with added flavorings. The cranberry industry explained that it had anticipated that the final guidance would extend to dried cranberries with added flavorings the same enforcement discretion as the other certain cranberry products covered under the draft guidance. Consequently, when the final guidance did not indicate an intent to extend enforcement discretion to dried cranberries with added flavorings, the cranberry industry sought additional time to comply with the Nutrition Facts final rule and Serving Size final rule.

We understand the change to exclude dried cranberries with added flavorings in the final guidance may have been unexpected for manufacturers of dried cranberries with added flavorings. We also understand that manufacturers of these dried cranberry products face operational constraints with respect to changing their labels by the compliance date for the final rules. To address these issues, through this guidance document, we are announcing our intent to

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exercise enforcement discretion with regard to compliance with the Nutrition Facts label final rule and the Serving Size final rule for certain dried cranberry products⁵ with added flavorings until July 1, 2020. We are taking this position because we recognize the importance of giving manufacturers of dried cranberries with added flavorings additional time to comply with the Nutrition Facts label final rule and Serving Size final rule.

V. References

The following references are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them in person at this location between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov> as these references are not copyright protected. Some may be available at the website address if listed. FDA has verified the website addresses, as of August 22, 2019, but websites are subject change over time.

1. U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015-2020 Dietary Guidelines for Americans. 8th Edition, p. 28. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.
2. Letter from Richard A. Stamm, Vice President, General Counsel, Ocean Spray Cranberries, Inc., submitted to Dr. Susan Mayne, Director, Center for Food Safety & Applied Nutrition, dated July 2, 2019.

⁵ See Footnote 2.