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# **The Declaration of Added Sugars on Honey, Maple Syrup, Other Single- Ingredient Sugars and Syrups, and Certain Cranberry Products: 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**

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# **The Declaration of Added Sugars on Honey, Maple Syrup, Other Single-Ingredient Sugars and Syrups and Certain Cranberry Products: Guidance for Industry<sup>1</sup>**

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on these topics. 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 as listed on the title page.

## **I. Introduction**

The purpose of this guidance is to provide clarification on the labeling requirements for single-ingredient packages and/or containers of pure<sup>2</sup> 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 Daily Value (DV) for added sugars on their labels. This 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. We intend to exercise our 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 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.

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<sup>1</sup> 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 at the U.S. Food and Drug Administration.

<sup>2</sup> In this guidance, we are using the terms “pure” and “100%” to distinguish the single-ingredient honey, maple syrup, and other single-ingredient sugar and syrup products from those that cannot properly be labeled “pure” or “100%” because they contain additional ingredients such as sweeteners or flavorings.

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We also intend to exercise our 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<sup>3</sup> products with endogenous (inherent) sugars, but no added sugars. The statement would provide flexibility to address concerns raised by stakeholders regarding the declaration of added sugars on certain cranberry products. We have information demonstrating that cranberries are a naturally tart fruit to which manufacturers sometimes add sugar in order to increase palatability. Therefore, certain dried cranberries and cranberry juice products have amounts of total sugars per serving up to levels comparable to the levels of non-cranberry comparable products. The comparable products contain equivalent amounts of total sugars, but their labels list zero “added sugars” because their fruit products are inherently sweet. Some stakeholders are concerned that consumers may think certain cranberry products are less nutritious than these comparable products because of the added sugars declaration.<sup>4</sup>

Finally, as discussed in section III, we are advising 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 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”) 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 33742 and 81 FR 34000).

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). With respect to our enforcement discretion policy pertaining to compliance with updated Nutrition Facts final rule and Serving Size final rule requirements on the particular products outlined above, this part of the guidance is being implemented without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)).

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<sup>3</sup> 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 grape juice to be comparable to a beverage made of sweetened cranberry juice and unsweetened raisins to be comparable to sweetened dried cranberries.

<sup>4</sup> The *2015-2020 Dietary Guidelines for Americans (2015-2020 Dietary Guidelines)* note that there is room for Americans to consume limited amounts of added sugars in their eating patterns and specifically mention that added sugars could be used to improve the palatability of nutrient dense foods, such as fruits and vegetables that are naturally tart (e.g., cranberries and rhubarb) (Ref. 1). The United States Department of Agriculture’s Food and Nutrition Service also provided an accommodation for dried whole fruits, or pieces, with nutritive sweeteners that are required for processing and/or palatability purposes, which included dried cranberries, for foods sold in schools (Ref. 2).

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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.

## **II. Background**

### **A. Dietary Guidelines for Americans**

The Department of Health and Human Services and the Department of Agriculture must jointly publish a report called the *Dietary Guidelines for Americans* every 5 years (7 U.S.C. 5441). The *Dietary Guidelines* form the basis of Federal nutrition policy, standards, programs, and education for the general public. The primary focus of the *Dietary Guidelines* is to promote overall health and prevent chronic disease in the United States. The *Dietary Guidelines* are the foundation of federal nutrition guidance and are fundamental in shaping federal policies and programs related to food, nutrition, and health.

The *2015-2020 Dietary Guidelines* includes a recommendation for healthy eating patterns that limit added sugars (including honey, syrups, and other caloric sweeteners) to less than 10 percent of calories per day (Ref. 3).

### **B. 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 of the DVs. The science underlying the Nutrition Facts label final rule, referenced above, is also reflected in the *2015-2020 Dietary Guidelines*.

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*

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*Guidelines* 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). 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)).

Pure (100%) honey, pure (100%) maple syrup, other single-ingredient sugars and syrups, and certain cranberry products sweetened with added sugars contribute to the DV of added sugars, regardless of whether they are added by consumers to foods (e.g., maple syrup poured over pancakes; sugar added to dried cranberries to increase palatability) or consumed in isolation (e.g., a spoonful of honey). FDA's definition encompasses the types of added sugars that were evaluated in the science underlying the *2015-2020 Dietary Guidelines* recommendation that no more than 10 percent of calories be from added sugars. These sugars were considered "empty calories" or "calories for other uses" in the USDA Food Patterns.

### **C. Draft Guidance**

In the *Federal Register* of March 2, 2018 (83 FR 8953), we made available a draft guidance for industry entitled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Draft Guidance for Industry; Availability" (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. We have considered comments to the draft guidance, and we have made modifications, where appropriate, that are now reflected in this final guidance.

### **D. Farm Bill**

After we published the Nutrition Facts label final rule and the Serving Size final rule, and draft guidance, the President signed into law the Agriculture Improvement Act of 2018 (Pub. L. 115-334) ("the Farm Bill"). Section 12516 of the Farm Bill states that the food labeling requirements under section 403(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)) shall not require that the Nutrition Facts label of any single-ingredient sugar, honey, agave, or syrup, including maple syrup, that is packaged and offered for sale as a single-ingredient food bear the declaration "Includes Xg Added Sugars." Therefore, single-ingredient sugars, honey, agave, and syrups, including maple syrup, do not need to have this statement of the number of grams of added sugars in a serving of their product on their label. At the same time, the Farm Bill did not change the requirement under the Nutrition Facts label final rule to include the percent DV for the contribution of sugars from these products to the added sugars in the diet.

## **III. Discussion**

Although the gram amount of added sugars in a serving of pure, single-ingredient sugars and syrups does not need to be declared on the label, these single-ingredient sugars and syrups are required under the Nutrition Facts label final rule to include the percent DV that they contribute

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to added sugars in the diet. The percent DV on pure, single-ingredient sugars and syrups provides important information to consumers about how the addition of sugar from these products contributes to their total daily diet. In the absence of the declaration of the amount of added sugars in a single-ingredient sugar or syrup product, a statement that includes information about the amount of sugars in a serving, as well as how that amount contributes to the consumer's diet and the percent DV for added sugars, provides information that can assist consumers in constructing a diet that is consistent with recommendations in the *2015-2020 Dietary Guidelines*.

Therefore, we intend to exercise enforcement discretion with respect to the use of a “†” symbol immediately following the added sugars percent DV and, per the Farm Bill, the term “Includes Xg Added Sugars” would not need to appear on the line on the Nutrition Facts label disclosing the added sugars percent DV. The “†” symbol should direct consumers to a statement that is truthful and not misleading within a footnote in the Nutrition Facts label box 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 footnote containing this factual statement should be placed beneath the required footnote that states, “The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice” (see illustration below).<sup>5</sup> Our intent to exercise enforcement discretion is limited to any pure, single-ingredient honey and maple syrup, and other pure, single-ingredient sugars and syrups.

We also intend to exercise our enforcement discretion for certain cranberry products described here (dried cranberries without added flavorings and cranberry beverages made up of cranberry juice that is sweetened with added sugars that provide an amount of total sugars in a serving that does not exceed the level of total sugars in a serving of a comparable product with no added sugars) to allow for the use of a “†” symbol immediately following the added sugars percent DV. The “†” symbol should direct consumers to a statement that is truthful and not misleading on the package outside the Nutrition Facts label.

Manufacturers could explain, through the use of such statements, that the sugars added to dried cranberries or the cranberry beverage product are meant to increase the palatability of the naturally tart fruit and that the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars. We have provided illustrations of such statements that we consider to be truthful and not misleading below.

At this time, we are not aware of products, other than the dried cranberry and cranberry beverage products previously discussed, for which the addition of sugars is intended to increase palatability, and for which the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars. Therefore, at

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<sup>5</sup> Note that the illustration provides an example of a truthful and not misleading statement about the gram amount of sugar added to the diet by one serving of the product and its contribution to the percent Daily Value for added sugars in the diet. FDA intends to exercise enforcement discretion for the use of any truthful and not misleading statement about the gram amount of sugar added to the diet by one serving of a single-ingredient sugar or syrup product and its contribution to the percent Daily Value for added sugars in the diet.

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this time we only intend to exercise enforcement discretion for cranberry products previously discussed with respect to the use of the “†” that would direct consumers to truthful and not misleading statements on the package outside the Nutrition Facts label, and do not intend to exercise enforcement discretion on other products (e.g., a granola bar or trail mix containing dried sugar-sweetened cranberries). We note that we would consider whether the same type of enforcement discretion discussed with respect to the cranberry products previously described might be warranted for other products where the addition of sugars is intended to increase palatability, such as naturally tart fruits, and for which the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars.

We consider that the exercise of enforcement discretion should apply to manufacturers’ use of statements that are truthful and not misleading within a footnote on packages and/or containers of pure honey, pure maple syrup, and other pure single-ingredient sugars and syrups. Furthermore, we consider that the exercise of enforcement discretion should apply for manufacturers to make factual statements to communicate additional information related to the declaration of added sugars on the label of cranberry beverage products and dried cranberry products that have been sweetened with added sugars and that provide total sugars at a level no greater than the amount of total sugars in comparable products with endogenous sugars and no added sugars. Adopting the intent to exercise enforcement discretion described above, under which these factual statements are referenced by the “†” symbol immediately following the added sugars percent DV, would address the concerns we heard about certain cranberry products and can provide information to assist consumers in determining how these foods and ingredients fit into their total daily diet. As consumers become accustomed to the new Nutrition Facts label and are educated on the added sugars declaration and the DV, we may re-evaluate our intent to exercise enforcement discretion for the placement of the “†” symbol in the Nutrition Facts label.

Additionally, we consider our consumer education to be an important component of the implementation of the new Nutrition Facts label requirements, especially for nutrients that will be declared on the label for the first time, such as added sugars, and our education efforts will include a focus on added sugars in the context of the entire label. We intend to continue to work with other Federal agencies, including other parts of the Department of Health and Human Services and the U.S. Department of Agriculture, state health departments, health professional organizations, food manufacturers, retailers, non-profit, and other organizations that have an interest and responsibilities in nutrition education and health promotion.

Finally, based on the implementation of the Farm Bill and further analysis of the added sugars requirements under the Nutrition Facts label final rule and Serving Size final rule, we are advising 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 updated labeling requirements set forth in the Nutrition Facts label final rule and the Serving Size final rule. We are taking this position because we recognize the importance of giving manufacturers of such products additional time to make appropriate label changes consistent with the Farm Bill and this final guidance. This means that, until July 1, 2021, we do not intend to pursue actions against the manufacturers of single-ingredient packages and/or



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containers of pure honey, pure maple syrup, and other pure sugars and syrups, as well as the dried cranberry and cranberry beverage products discussed previously in this guidance, that do not meet all of the provisions outlined in the Nutrition Facts label final rule and Serving Size final rule.

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**Illustration of Nutrition Facts label for pure honey, pure maple syrup, or other single-ingredient sugars or syrups with “†” symbol leading to a footnote<sup>6</sup>**

<b>Nutrition Facts</b>	
16 servings per container	
<b>Serving size</b>	<b>1 Tbsp. (21g)</b>
<b>Amount per serving</b>	
<b>Calories</b>	<b>60</b>
<b>% Daily Value*</b>	
<b>Total Fat</b> 0g	<b>0%</b>
Saturated Fat 0g	<b>0%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 0mg	<b>0%</b>
<b>Total Carbohydrate</b> 17g	<b>6%</b>
Dietary Fiber 0g	<b>0%</b>
Total Sugars 17g	<b>34%<sup>†</sup></b>
<b>Protein</b> 0g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 0mg	0%
<small>* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.</small>	
<small><sup>†</sup> One serving adds 17g of sugar to your diet and represents 34% of the Daily Value for Added Sugars.</small>	

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<sup>6</sup> The illustration provides one example of a truthful and not misleading statement about the gram amount of sugar added to the diet by one serving of the product and its contribution to the percent Daily Value for added sugars in the diet.

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**Illustration of Nutrition Facts label for cranberry juice or dried sweetened cranberries with “†” symbol leading to a factual statement outside the Nutrition Facts label**

<b>Nutrition Facts</b>	
8 servings per container	
<b>Serving size 8 fl oz (240mL)</b>	
<b>Amount per serving</b>	
<b>Calories</b>	<b>110</b>
<b>% Daily Value*</b>	
<b>Total Fat</b> 0g	<b>0%</b>
Saturated Fat 0g	<b>0%</b>
Trans Fat 0g	
<b>Cholesterol</b> 0mg	<b>0%</b>
<b>Sodium</b> 5mg	<b>0%</b>
<b>Total Carbohydrate</b> 27g	<b>10%</b>
Dietary Fiber 0g	<b>0%</b>
Total Sugars 25g	
Includes 23g Added Sugars	<b>46%†</b>
<b>Protein</b> 0g	
Vitamin D 0mcg	0%
Calcium 0mg	0%
Iron 0mg	0%
Potassium 40mg	0%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

**Recommended factual statements**

† Sugars added to improve the palatability of naturally tart cranberries. The 2015-2020 Dietary Guidelines for Americans state that there is room for limited amounts of Added Sugars in the diet, including from nutrient dense foods, like naturally tart fruit.

† Sugars added to improve the palatability of naturally tart cranberries.

† Sugars added to improve palatability.

† Sugars added to improve the palatability of naturally tart cranberries. The 2015-2020 Dietary Guidelines for Americans recommends limiting calories from added sugars to no more than 10% each day.

## **IV. 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 May 6, 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. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.
2. A Guide to Smart Snacks in School. Available at [https://fns-prod.azureedge.net/sites/default/files/tn/508\\_USDASmartSnacks\\_508\\_82218.pdf](https://fns-prod.azureedge.net/sites/default/files/tn/508_USDASmartSnacks_508_82218.pdf)
3. U.S. Department of Health and Human Services and U.S. Department of Agriculture. 2015-2020 Dietary Guidelines for Americans. 8<sup>th</sup> Edition, p. 28. December 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>.