CENTER FOR
Science IN THE
Public Interest
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Nutrition Action Healthletter

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Dr. Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products; Draft Guidance for Industry; Availability; Docket No. FDA–2018–D–0075

Dear Commissioner Gottlieb:

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the Food and Drug Administration's proposed rule and draft guidance for industry regarding the declaration of added sugars on honey, maple syrup, and certain cranberry products.

It is important to ensure that manufacturers' statements about the meaning of "added sugars" on all Nutrition Facts labels are truthful and not misleading. If this draft guidance is not carefully considered, such statements may lead consumers to erroneously conclude that the added sugars in honey, maple syrup, and some cranberry products are inherently less harmful than other added sugars. In fact, FDA's final Nutrition Facts label rule considers all forms of added sugars—including honey, maple syrup, and sugars added to sweeten cranberry products—to be equivalent, and guidance that permits any statement that appears to undermine this conclusion is both outside the scope of the rule and contrary to it. Furthermore, such a statement is also contrary to the science on added sugars.

CSPI is a non-profit consumer education and advocacy organization that, since 1971, has worked to improve the public's health through better nutrition and food safety. CSPI's work is supported primarily by roughly 500,000 subscribers to its *Nutrition Action Healthletter*, one of the nation's largest-circulation health newsletters. CSPI is an independent organization that does not accept government or corporate donations. CSPI has advocated for decades to ensure that Nutrition Facts labels and claims on food labels are truthful and not misleading.

FDA's draft guidance would allow manufacturers of single-ingredient honey and maple syrup to place a dagger adjacent to their Nutrition Facts declaration of added sugars with an accompanying "factual statement" to indicate that these sugars are naturally occurring in the honey or maple syrup. It would also allow manufacturers of cranberry juice and dried cranberry products with added sugars to use the dagger with a statement that sugars are added because of cranberries' tartness and that the *Dietary Guidelines* allows room for

such sugars in the diet. We respectfully submit the following comments regarding FDA's draft guidance on the use of a dagger and accompanying "factual statement" about the Nutrition Facts label declaration of added sugars in honey, maple syrup, and certain cranberry products.

I. FDA cannot allow companies to write their own "factual statement."

The purpose of the statement, according to the draft guidance, is to prevent consumer confusion. FDA indicates that it is taking this action to address stakeholders' concerns that consumers might misinterpret the added sugars declaration to mean that maple syrup or honey have been combined with sweeteners like corn syrup, or to mean that dried cranberries and cranberry juice products with added sugars are "less nutritious" than other dried fruits or 100% juices with no added sugars.

However, allowing companies to write their own statements would sow far greater confusion. Consumers comparing brands of honey, for example, might interpret different statements to mean that one brand has more or less added sugar than another. Companies' statements, inevitably informed by marketing and competitive concerns, might also imply that there are health benefits of consuming added sugars from honey or maple syrup rather than sugar beets or cane.

Instead, FDA should provide clear and standardized wording for an optional statement on each type of product (honey, maple syrup, and cranberry products). Because the statements are referenced by a dagger within the Nutrition Facts label, the agency is obligated to ensure that they are consistent in supporting consumers' efforts to maintain healthy dietary practices, rather than, in effect, conferring the legitimacy of the Nutrition Facts label upon divergent, potentially self-serving industry statements.

II. FDA should conduct consumer testing of any proposed "factual statement" to ensure that it improves understanding and prompts healthier choices.

In the final Nutrition Facts rule, FDA required the declaration of added sugars—for all foods and beverages—because consuming too much added sugar dilutes nutrient density, increases caloric intake, and is associated with an increased risk of cardiovascular disease.[1] In addition, the Daily Value for added sugars tells consumers how much of a day's worth of added sugars each serving of a food provides. Therefore, to be consistent with the rule, FDA must ensure that any statements about the added sugars declaration not lead consumers to devalue or disregard the labeling and percent Daily Value for added sugars, potentially leading to an industry-driven increase in consumption of particular products, or to an increase in consumers' overall intake of added sugars. Without consumer studies to ensure that these statements are not misleading, FDA risks undermining critical advice that the new Nutrition Facts label gives to consumers and diminishing its benefits to public health.

III. FDA should revoke permission for such "factual statements" about the added sugars declaration one year after the Nutrition Facts label compliance date.

FDA's draft guidance explains: "[a]s consumers become accustomed to the new Nutrition Facts label and educated on the added sugars declaration and the Daily Value, we may re-

evaluate the placement of the '†' symbol in the Nutrition Facts label." We agree that the dagger and statement are likely to become unnecessary once consumers are familiar with the new Nutrition Facts label and the definition of added sugars through continued exposure in the marketplace and consumer education. Given the new Nutrition Facts label's swift adoption—an estimated 15,000 products bore it by the end of 2017[2]—most consumers will be familiar with added sugars labeling well before the compliance dates of January 1, 2020 and January 1, 2021. Thus, FDA should expeditiously revoke the provision for the "†" symbol and statements about honey, maple syrup, and cranberry products within a year of compliance.

We now consider each of the products (cranberry juice, dried cranberries, and honey/maple syrup) implicated by the draft guidance in turn.

IV. FDA should not permit a "factual statement"—especially one citing nutrient density—on cranberry juice products that contain added sugars.

The example statement that FDA provided in the draft guidance reads, **"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, especially from nutrient dense food like naturally tart cranberries."** This sounds like advertising copy, not a clear statement of public health information. Such a statement misleads consumers about both the FDA's Daily Value for added sugars and the *Dietary Guidelines*' advice concerning cranberry juice drinks. As we state in the next section, we oppose its use on all cranberry products, but in particular the statement is inappropriate and misleading when used on cranberry juice drinks.

First, the sample statement misleads consumers and undermines the credibility of FDA's Daily Value (DV) for added sugars by implying that cranberry juice drinks contain a "limited" amount of added sugars. A serving of cranberry juice cocktail contains approximately 50% of a day's added sugar (see Appendix). Yet the proposed statement implies misleadingly that this is a "limited amount." In fact, FDA regulations define 20% or more of the DV as a "high" amount; disqualify products that contain 20% or more of the DV per serving for fat, saturated fat, cholesterol, or sodium from making a health claim; and require a disclosure when those products make certain nutrient content claims.[3] FDA should only allow a statement to use words like "a limited amount" to refer to levels at or below approximately 5% of the DV, which is consistent with FDA's definition of "low" for fat, saturated fat, and sodium.[4] In addition, unless and until FDA defines such a "low" nutrient content claim for added sugars, a statement referring to a "limited amount" of added sugars in a product is in fact misleading *per se*.

Similarly, the proposed statement misleads consumers by implying that cranberry juice drinks are nutrient dense. "Cranberry juice cocktail" typically contains no more than 15% to 30% cranberry juice, plus water and added sugars. Such drinks therefore contain *fewer* nutrients than 100% juice blends that contain cranberry juice and other fruit juices, or than other types of 100% fruit juice (Table 1)—not more, as FDA's proposed statement implies. Orange, grapefruit, pineapple, and prune juices are all far more nutrient dense than cranberry juice cocktail. (Grape and apple juice would also be more nutrient dense than cranberry juice cocktail if cranberry juice cocktail did not have added vitamin C.) The

difference in nutrient density between juice drinks and many 100% fruit juices illustrates why the added-sugars declaration and percent Daily Value on Nutrition Facts labels are helpful to consumers, so long as they are not undercut by statements such as that proposed by FDA.

	Orange Juice[1]	Grapefruit Juice	Prune Juice	Pineapple Juice	Grape Juice	Apple Juice	Cranberry Juice Cocktail
Calories	120	100	180	130	150	110	140
Sugar (g)	21	20	42	25	36	24	30
% Daily Value							
Calcium	2%	3%	2%	2%	2%	2%	1%
Iron	2%	1%	17%	4%	4%	2%	1%
Magnesium	6%	5%	9%	7%	6%	3%	1%
Potassium	9%	8%	15%	7%	6%	5%	1%
Zinc	2%	1%	5%	3%	2%	0%	1%
Copper	12%	9%	19%	19%	5%	3%	3%
Manganese	2%	2%	17%	55%	26%	8%	5%
Selenium	0%	1%	3%	0%	0%	0%	1%
Vitamin C	93%	96%	12%	28%	0%	2%	119%[2]
Thiamin	10%	14%	3%	12%	4%	4%	0%
Riboflavin	7%	4%	14%	4%	3%	3%	0%
Niacin	4%	4%	13%	3%	2%	1%	1%
Pantothenic acid	10%	14%	5%	3%	2%	2%	3%
Vitamin B-6	11%	6%	33%	15%	5%	3%	0%
Folate	12%	9%	0%	11%	0%	0%	0%
Vitamin A	1%	1%	0%	0%	0%	0%	0%
Vitamin E	3%	4%	2%	0%	0%	0%	4%
Vitamin K	0%	0%	7%	1%	1%	0%	2%

[1] USDA National Nutrient Database entries (left to right): 09209, 09123, 09294, 09273, 09135, 09016, 14242.
[2] Contains added vitamin C (ascorbic acid).

Table 1. Nutrients in 1 cup of 100% orange, grapefruit, prune, pineapple, grape, and apple juices, and in 1 cup of cranberry juice cocktail.
Source: USDA National Nutrient Database for Standard Reference

In addition to the fact that cranberry juice drinks are *not* nutrient dense, the phrase "especially from nutrient dense food like naturally tart cranberries" is likely to mislead consumers because it implies that cranberry products are more healthful than other foods. It does this in two ways: 1) "especially" implies that the *Guidelines* encourages people to consume more cranberry juice drinks in particular, and 2) "nutrient dense food" is not further defined. Many consumers are unlikely to understand that "nutrient dense food" encompasses a wide variety of unprocessed foods, including "[a]ll vegetables, fruits, whole grains, seafood, eggs, beans and peas, unsalted nuts and seeds, fat-free and low-fat dairy products, and lean meats and poultry," according to the *Guidelines'* definition.[5] FDA's sample statement implies that sugar-sweetened cranberry juice drinks are inherently more healthful than many other foods. Such a statement is unscientific, highly misleading, and inconsistent with the *Dietary Guidelines for Americans*.

Finally, the example statement proposed in the FDA's draft guidance is factually inaccurate with respect to cranberry juice drinks, because it incorrectly applies the *2015-2020 Dietary Guidelines for Americans* statement about *cranberries* (a food) to *cranberry juice drinks* (a beverage). In fact, the *2015-2020 Dietary Guidelines for Americans* makes it clear that cranberry juice products with added sugars are juice drinks (*i.e.*, sugar-sweetened beverages) and discourages their consumption because juice drinks are less healthy and contain fewer nutrients than 100% fruit juice. As the *Guidelines* says, "When juices are consumed, they should be 100% juice, without added sugars…Sweetened juice products with minimal juice content, such as juice drinks, are considered to be sugar-sweetened beverages rather than fruit juice because they are primarily composed of water with added sugar."[6] The *Guidelines* only acknowledges a role for added sugar in sweetening naturally tart foods, not drinks, noting that "[t]here is room for Americans to include limited amounts of added sugars in their eating patterns, including to improve the palatability of some nutrient-dense **foods**, such as fruits and vegetables that are naturally tart (*e.g.*, cranberries and rhubarb)." [*Emphasis added*][7] This statement, which was specific to cranberries consumed as a food, is not factually accurate when applied to cranberry juice drinks.

Such a misleading and factually inaccurate statement is also entirely unnecessary. There is no reason (other than marketing that benefits the cranberry industry) for a statement to further qualify—and particularly as "nutrient dense" or a "limited amount"—the nutritional value or percent Daily Value of added sugars contained in these products. The companies cannot escape the fact that their products come with more undesirable characteristics and fewer nutrients than similar products—and the Nutrition Facts panel simply reflects that. It is not FDA's responsibility to compensate for these characteristics of the product. Accordingly, we urge the FDA to amend the guidance to specify that terms describing cranberry juice cocktails as "nutrient dense" or implying that they contain a "limited amount" of added sugar may not be included in an asterisk to the Nutrition Facts label, or elsewhere on the product label.

V. FDA should not permit a "factual statement" on sweetened dried cranberries.

FDA should not permit the example "factual statement" on sweetened dried cranberries either, because it implies that sweetened dried cranberries are uniquely nutritious. Such a statement may promote excess consumption of dried cranberries instead of fresh or frozen fruit, which is less calorie dense. For example, just ¼ cup of dried sweetened cranberries contains as many calories (130) as 1½ cups of whole blueberries or 2½ cups of sliced strawberries. In addition, such a concession for sweetened dried cranberries would likely prompt similar requests from companies that sell dried blueberries or tart cherries,[8] which would further confuse consumers and unduly delay implementation of the new Nutrition Facts label.

However, even if FDA decides to permit a statement on sweetened dried cranberries that do not exceed the total sugar levels of unsweetened dried fruits, such as raisins, the agency should not permit the statement on dried cranberries that contain other caloric ingredients that dilute their nutrient density. For example, FDA should not allow the statement on sweetened dried cranberries that are covered in chocolate or so-called "yogurt" (largely

sugar and palm kernel oil) coatings. Likewise, the statement should not be permitted on multi-ingredient products that contain other sources of added sugars (such as trail mixes, cold cereals, and granola bars).

In addition, assuming FDA includes any statement, it should revise its example statement to avoid misleading consumers about the benefits of calorie-dense dried fruits. CSPI recommends a short version of FDA's example statement that includes only the first sentence: **"Sugars added to improve the palatability of naturally tart cranberries."** This sentence is clear, simple, and accurately conveys that cranberries inherently require added sugar for palatability.

In contrast, the phrase "especially from nutrient dense food like naturally tart cranberries" in FDA's sample is likely to mislead consumers for two reasons, as previously stated for juice drinks: 1) "especially" implies that the *Guidelines* encourages consumers to consume more dried cranberries in particular, when it doesn't, and 2) "nutrient dense food" is not further defined. As previously stated, many consumers are unlikely to understand that "nutrient dense food," by the *Guidelines*' definition, encompasses a wide variety of unprocessed foods.[9] FDA's misleading sample statement implies that sweetened dried cranberries are inherently more healthful than many other foods.

Furthermore, as noted above, the phrase "the 2015-2020 Dietary Guidelines for Americans state that there is room for limited amounts of Added Sugars in the diet" implies that dried cranberries contain a low amount of added sugars. A ¼ cup serving of sweetened dried cranberries contains roughly 50% of the DV for added sugar (see Appendix). As we state in the prior section, this amount far exceeds FDA's regulations concerning "high" levels of other nutrients in foods. Use of the term "limited amount of added sugars" on dried sweetened cranberry products is therefore misleading.

Alternatively, if FDA decides to include information from the *Guidelines* in its example statement, CSPI suggests the following wording: **"Sugars are added because cranberries are naturally tart. The *2015-2020 Dietary Guidelines for Americans* recommend no more than 50 grams of added sugars per day (the Daily Value)."** This wording addresses the issues noted above because it omits the word "limited," and it clarifies that the sugars added to cranberries count toward the 50-gram Daily Value for added sugars.

VI. A "factual statement" for honey and maple syrup products is unnecessary because the product names and an optional ingredients list convey the same information. Moreover, FDA's example statement is extremely misleading to consumers.

The FDA draft guidance's example "factual statement" for honey states: "All these sugars are naturally occurring in honey." Companies claim that this statement is needed because consumers might misinterpret the added-sugars declaration to mean that maple syrup or honey has been adulterated with sweeteners like corn syrup. While we understand that concern, a dagger and "factual statement" is an unnecessary and potentially confusing fix.

The "factual statement" is unnecessary because companies can use far more prominent product names or front-of-package claims to describe the contents and assure shoppers; *e.g.*, "100% pure honey" or "100% pure maple syrup" (Figure 1). Companies also have the

option of placing an ingredients list immediately below or adjacent to the Nutrition Facts label. An ingredients list clarifies that the product contains only honey or maple syrup with no added sweeteners (Figure 2).

Figure 1. Maple syrup with a prominent "100% pure" claim.
Source: Label Insight

Figure 2. Honey with the new Nutrition Facts label, a "100% pure" claim, and an ingredients list.
Source: Label Insight

If FDA permits honey and maple syrup companies to use a factual statement, it will likely face similar requests from companies that market single-ingredient packages of agave syrup, molasses, brown rice syrup, sugar, and other sweeteners. In fact, the International Sugar Trade Coalition has already made that request.[10] Instead of littering so many Nutrition Facts labels with daggers and potentially misleading statements, FDA should rely on ingredients lists, product names, and Nutrition Facts consumer education efforts (by FDA or concerned companies). The *unqualified* disclosure of "added sugars" on packages of

single-ingredient sweeteners such as honey, maple syrup, cane sugar, and agave syrup is an important educational tool to inform consumers that these products contribute added sugars—and essentially no other nutrients—to their diets.

The proposed example "factual statement" is also extremely misleading to consumers, undermining efforts to educate consumers about the dietary recommendations for added sugars. Many consumers remain unfamiliar with the concept of added sugars, which is intended to describe sugars that have been concentrated or refined for use as sweeteners, as opposed to sugars that are present naturally and without further refinement in fruits, vegetables, and milk. Many consumers may wrongly believe that because honey and maple syrup are extracted and concentrated through biological processes (in the case of honey), or traditional methods (maple syrup), these products are healthier than other sources of added sugars, such as from sugar beets, corn, or cane. They may also wrongly infer that these sugars should not count toward their Daily Value for added sugar. In fact, the sugars in honey and maple syrup are not more healthful or less caloric than other added sugars, and consumers should consider these sources as contributing to their Daily Value for added sugar. Rather than correct this misperception by educating consumers, the FDA's example "factual statement" fuels confusion by stating that the "added sugar" in honey is "naturally occurring."

If FDA proceeds with permitting a dagger and "factual statement" for honey and maple syrup, it should revise the statement to avoid misleading consumers. Instead, FDA should require a specific statement that educates consumers about "added sugars" by clarifying that the sugars present in honey or maple syrup count toward the Daily Value. For example: **"The sugar in honey counts toward your Daily Value for added sugars."** (Or **"Sugars from honey count toward your Daily Value for added sugars."**) Such alternatives would be far more accurate, clear, and useful to consumers. Alternatively, FDA's statement could emphasize that the unadulterated product contains only honey or maple syrup with no other ingredients, such as: **"This product contains honey with no other ingredients."** (Or **"This product contains maple syrup with no other ingredients."**)

VII. FDA should not exercise enforcement discretion to give products affected by the draft guidance an additional year to comply with the new Nutrition Facts label.

The agency should not grant products affected by the draft guidance an additional year to comply beyond the proposed Nutrition Facts label delay. This enforcement discretion would amount to a delay to January 1, 2021, and January 1, 2022, for large and small manufacturers, respectively. Further delay for an *optional* label statement is unnecessary; updating the Nutrition Facts label is already long overdue.[11] In addition, the absence of the new Nutrition Facts label on affected products in the interim could harm the public's health. New Nutrition Facts labels include the line for added sugars and percent Daily Value, the refreshed design that includes a larger, bolder type size for key information (including calories), and clearer labeling of the nutrient content in a single-serving container. This proposed unwarranted delay would also prolong the confusing and unfair (to compliant companies) hodgepodge of new and old Nutrition Facts labels in the marketplace.

Furthermore, many manufacturers of cranberry juice drinks, honey, and maple syrup have already adopted the new Nutrition Facts label (see Appendix). This widespread early adoption demonstrates that implementing the new label on these products without an optional dagger and statement is clear, feasible, and acceptable to manufacturers. For manufacturers that wish to use an optional dagger and statement, the delayed compliance dates of January 1, 2020, and January 1, 2021, for large and small manufacturers, respectively, already provide more than ample time for FDA to finalize this guidance.

VIII. Conclusion

In conclusion, FDA must ensure that manufacturers' statements about the meaning of "added sugars" on all Nutrition Facts labels are truthful and not misleading. Consumers would be best served if FDA did not permit a "factual statement" qualifying the added sugars in cranberry, honey, and maple products. At a minimum, if the agency allows for a "factual statement," it should require a specific statement in a manner described in these comments, rather than authorizing manufacturers to craft their own statements and providing examples that are misleading to consumers.

Endnotes

[1] 81 FR 103 at 33799.

[2] Food Dive: Poll: Consumers appreciate transparency of nutrition labels. *Label Insight.* October 3, 2017. Available at: https://www.labelinsight.com/press/food-dive-poll-consumers-appreciate-transparency-of-nutrition-labels.

[3] 21 CFR 101.54, 101.14, and 101.13.

[4] 21 CFR 101.61 and 101.62.

[5] U.S. Department of Health and Human Services and U.S. Department of Agriculture. *2015–2020 Dietary Guidelines for Americans*. Eighth Edition. December 2015. Available at: https://health.gov/dietaryguidelines/2015/resources/2015-2020_Dietary_Guidelines.pdf (p. 94).

[6] Ibid (p. 21-22).

[7] Ibid (p. 31).

[8] 81 FR 146 at 50143.

[9] U.S. Department of Health and Human Services and U.S. Department of Agriculture, op. cit. (p. 94).

[10] International Sugar Trade Coalition. *Comments on the Draft Guidance Entitled "The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry."* March 2, 2018. Available at: https://www.regulations.gov/document?D=FDA-2018-D-0075-0036.

[11] See also CSPI's comments Re: Docket No. FDA-2012-N-1210; Proposed Extension of Compliance Dates. https://cspinet.org/sites/default/files/attachment/Center%20for%20Science%20in%20the%20Public%20Interest%20Comment%20on%20Nutrition%20Facts%20label%20extension.pdf.

Appendix

Examples of Cranberry, Maple, and Honey Products with the New Nutrition Facts Label

Source: Label Insight

Cranberry Juice Cocktail

Kirkland Signature Organic Cranberry Juice Cocktail

Nice! Cranberry Juice Cocktail

Meijer Cranberry Cocktail

Minute Maid Cranberry Grape Flavored Juice Beverage

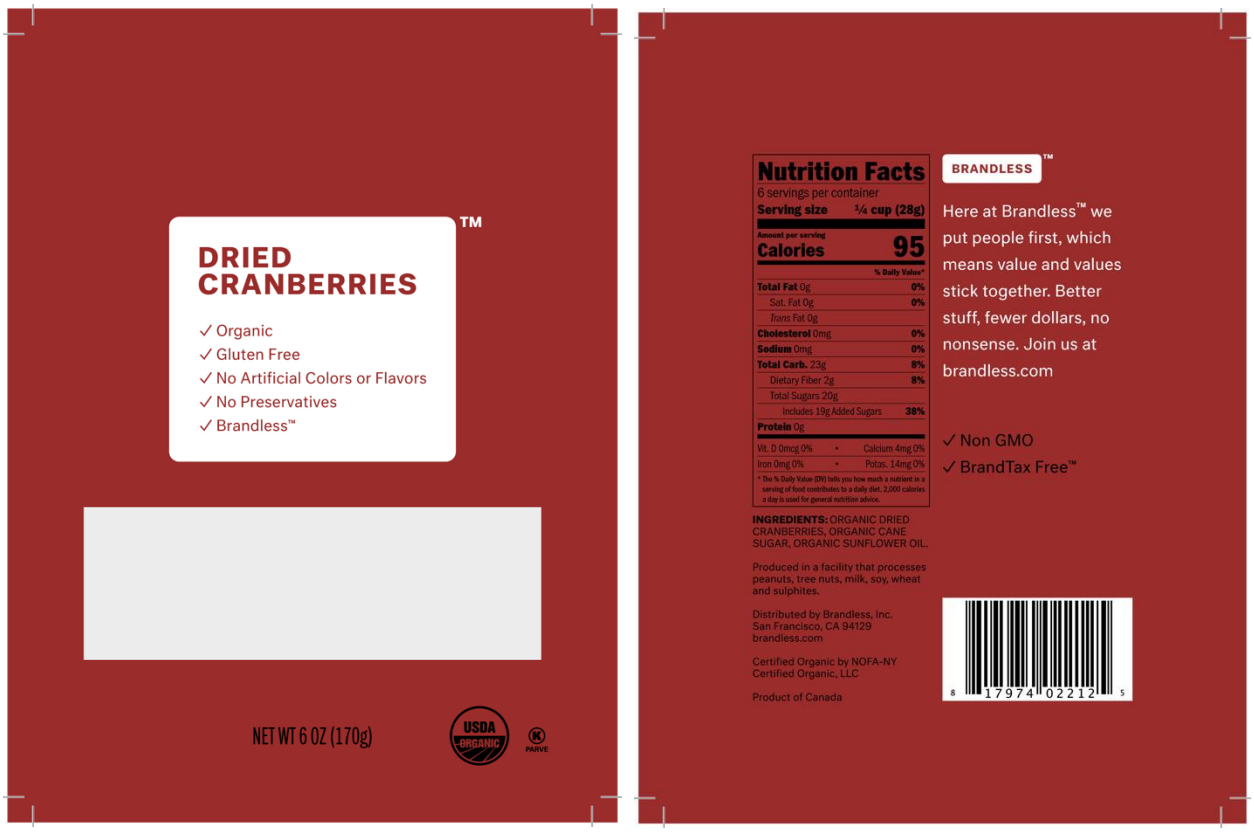
Ahold Cranberry Grape Flavored Juice Cocktail

Brookshire's Cranberry Pineapple Juice Cocktail

Sweetened Dried Cranberries

Signature Farms Dried Cranberries

Wild Harvest Organic Dried Sweetened Cranberries

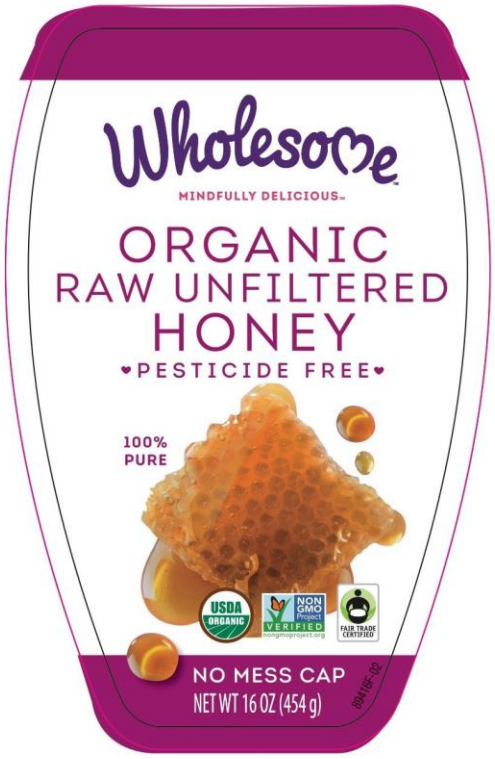


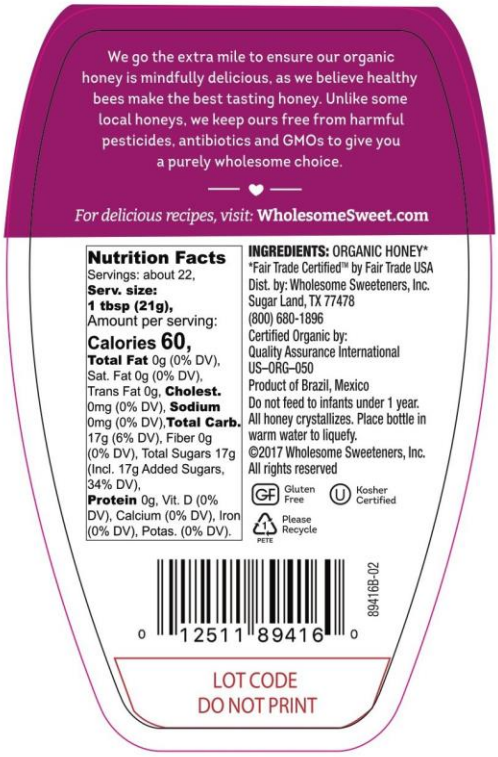
Brandless Dried Cranberries

Maple Syrup

O Organics 100% Pure Maple Syrup

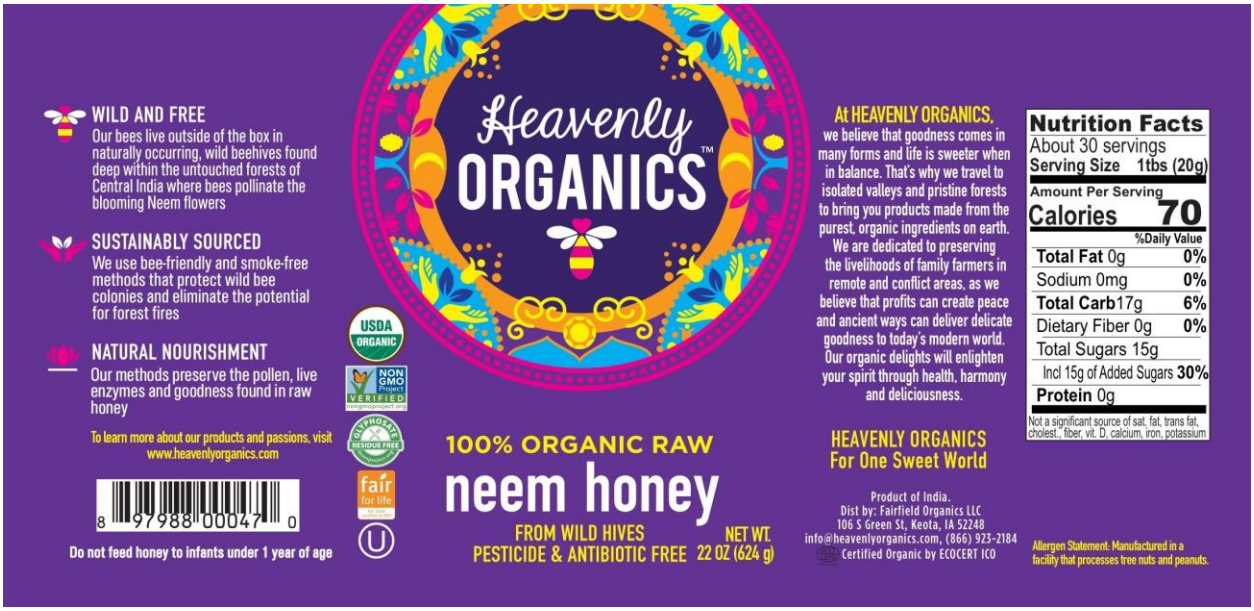
Honey





Wholesome Organic Raw Unfiltered Honey

Wholesome Spreadable Organic Raw Unfiltered Honey



Heavenly Organics 100% Organic Raw Neem Honey

Heavenly Organics 100% Organic Raw White Honey