UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BONUMOSE, INC.,

Plaintiff,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 23-645 (RDM)

MEMORANDUM OPINION

Plaintiff Bonumose, Inc. ("Bonumose" or "the company") is a food ingredients manufacturer that produces D-Tagatose ("tagatose"). Dkt. 23-1 at 11; *see also* Dkt. 37-5 at 89. Tagatose is a monosaccharide that food producers use as an alternative to substances that are traditionally known as sugars ("traditional sugars"). Dkt. 23-1 at 11 (citing Dkt. 37-2 at 77). Although tagatose can be used as sweetener in the place of traditional sugars, Bonumose claims that tagatose does not have the same downsides that traditional sugars have. For example, the company states that "[t]agatose has been scientifically shown to: (a) aid in glycemic control; (b) reduce risks of tooth decay; (c) function as prebiotic; (d) reduce cardiovascular disease risk factors; (e) assist in body weight control; (f) support hematological health; and (g) function as an antioxidant." *Id.* Tagatose also generates less energy per gram than do traditional sugars: tagatose creates 1.5 kcal/gram of energy whereas traditional sugars create 4 kcal/gram.[1] Dkt. 37-

[1] What we refer to as "calories" in ordinary usage is actually a measure of kilocalories per gram (kcal/g). A calorie is defined as "the amount of heat energy needed to raise the temperature of a kilogram of water 1°C (determined at 14.5°C to 15.5°C) and is the unit that has been traditionally used for expressing the energy value of foods." Dkt. 37-2 at 186.

2 at 186, 188. Despite these differences between tagatose and traditional sugars, the Food and Drug Administration's ("FDA") food labeling regulations treat tagatose the same as traditional sugars. Specifically, the FDA requires that food products exhibit a nutrition label that declares how much total sugar and added sugar is in the food product, including how much tagatose is in the product. *See* 21 C.F.R § 101.9(c)(6)(iii).

Bonumose brings this suit to challenge the FDA's decision to treat tagatose like a traditional sugar for the purposes of food labeling. Bonumose brings two claims. The first alleges that the regulations that require food labels to identify the amount of added sugar in food products violate the First Amendment of the U.S. Constitution as applied to products that contain tagatose. Bonumose's second claim is brought under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.*, and alleges that the FDA's decision to deny Bonumose's petition to exempt tagatose from 21 C.F.R. § 101.9(c)(6)(iii) was arbitrary and capricious and not in accordance with law, *see* 5 U.S.C. § 706(2)(A).

Bonumose has moved for summary judgment on both claims. Dkt. 23. The FDA has moved to dismiss Bonumose's constitutional claim, arguing that the company lacks standing to pursue it, and the agency has cross-moved for summary judgment on Bonumose's APA claim. For the reasons that follow, the Court will **GRANT** Bonumose's motion for summary judgement on its APA claim; will **DENY** the FDA's motion for summary judgment on the APA claim; and will **DENY** both parties' motions for summary judgment on the First Amendment claim.

I. BACKGROUND

A. Statutory and Regulatory History

"[T]o protect the health and safety of the public at large," the Food, Drug, and Cosmetic Act ("FDCA") requires that foods sold to consumers be accurately labeled. *POM Wonderful*

LLC v. Coca-Cola Co., 573 U.S. 102, 108 (2014); *see* 21 U.S.C. § 343(a), (q)(1). In particular, food products must exhibit nutrition labels that declare: (1) "the amount [of the food product] customarily consumed," known as the "serving size;" (2) the number of servings per container; (3) the total number of calories per serving size (or other unit of measure); and (4) "the amount of the following nutrients" in the food product: "total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein." *Id.* § 343(q)(1). This list of nutrients is nonexhaustive, however, and the statute authorizes the FDA to issue regulations that change what nutrients must be included on food labels if doing so would "assist consumers in maintaining healthy dietary practices." *Id.* § 343(q)(2).

In 2016, the FDA exercised its authority to include "added sugars" on the list of nutrients addressed by nutrition labels. *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742 (May 27, 2016) (hereafter "Added Sugar Final Rule"). 21 C.F.R. § 101.9(c)(6)(iii) provides that the nutrition label on food must include, with some exceptions, "[a] statement of the number of grams of added sugars in a serving." "Added sugars" are "free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose)," "sugars from syrups and honey," and certain "sugars from concentrated fruit or vegetable juices" that are "either added during the processing of foods, or are packaged as such." *Id.* § 101.9(c)(6)(ii), (iii).

The FDA decided to require the disclosure of added sugars in food products based on research that showed the health benefits of reducing the consumption of added sugars. In reaching this conclusion, the FDA relied upon two reports. The first is the 2010 Dietary Guidelines for Americans ("DGA"). *See* Added Sugar Final Rule, 81 Fed. Reg. at 33799. At least every five years, the U.S. Department of Agriculture ("USDA") and the U.S. Department of

Health and Human Services ("HHS") jointly publish a report containing nutritional and dietary information and guidelines for the general public based on a preponderance of current scientific and medical knowledge. *See* 1990 National Nutrition Monitoring and Related Research Act, 7 U.S.C. § 5341, *et seq*. In 2010, the DGA recommended that American adults reduce their added sugar intake. *See generally*, USDA & HHS, Dietary Guidelines for Americans: 2010, https://perma.cc/GP4D-L6CW. Helping to inform the DGA is the Dietary Guidelines Advisory Committee ("DGAC"), which is a committee of public health and nutrition experts. In February 2015, the DGAC released a report that reaffirmed the recommendations in the 2010 DGA, including the recommendation that Americans reduce their added sugar intake. Added Sugar Final Rule, 81 Fed. Reg. at 33799. In its report, the DGAC concluded "that there is strong and consistent evidence that healthy dietary patterns characterized, in part, by lower intakes of sugar-sweetened foods and beverages . . . are associated with a reduced risk of [cardiovascular disease]." *Id.*; *see also* Dkt. 37-6 at 103–110 (2015 DGAC Report).

Following the release of these two reports, which both recommended that Americans reduce their added sugar intake, the FDA considered whether to amend its food labeling regulations to require the disclosure of the amount of added sugar in food products. As part of this process, the FDA reviewed the evidence that the 2015 DGAC and the 2010 DGA had relied upon and it agreed with the conclusions both reports had reached:

> The need for a mandatory declaration of added sugar is supported by strong and consistent evidence that dietary patterns characterized by higher consumption of vegetables, fruits, whole grains, low-fat dairy, and seafood, and lower consumption of red and processed meat, and lower intakes of refined grains, and sugar-sweetened foods and beverages relative to less healthy dietary patterns; regular consumption of nuts and legumes; moderate consumption of alcohol; lower in saturated fat, cholesterol, and sodium and richer in fiber, potassium, and unsaturated fats are associated with a decreased risk of [cardiovascular disease]. The scientific evidence from the 2010 DGA supporting that consumption of excess calories from added sugars can lead to a less nutrient-

> dense diet, current consumption data showing that Americans are consuming too many calories from added sugars, and the strong evidence that greater intake of sugar-sweetened beverages is associated with increased adiposity in children also support mandatory declaration of added sugars.

Added Sugar Final Rule, 81 Fed. Reg. at 33800.

In particular, the FDA focused on the concept of "empty calories" as described by the DGAC's 2015 report. *See, e.g., id.* at 33835. The report explained that "empty calories" are calories from foods—such as "[s]olid fats that occur naturally in foods such as meat, dairy, and some tropical foods (e.g., coconut), and sugars that are added to foods either by the consumer or by food manufacturers"—that "both provide calories, but [provide] few or no nutrients." Dkt. 37-6 at 55. Foods that contain large amounts of empty calories are problematic, the FDA explained in the preamble to the final added sugar rule, because they account for "excess calories in the U.S. diet" and "make it difficult for consumers to meet nutrient needs within their calorie limits." Added Sugar Final Rule, 81 Fed. Reg. at 33815; *see also id.* at 33807 ("[I]t would be extremely difficult for individuals consuming large amounts of empty calories from sugar-sweetened foods and beverages to be able to consume enough of the other components of a healthy dietary pattern to be able to receive a high diet quality score.").

Consistent with that concern, the FDA decided that it would require food producers to declare on the labels of their products how much added sugar was in the food products. The final rule provides in relevant part: "[t]he declaration of nutrition information on the label and in labeling of a food shall contain information about the level of . . . added sugars. 21 C.F.R. § 101.9(c)(6). "Added sugars content shall be indented under Total Sugars and shall be prefaced with the word "Includes" followed by the amount (in grams)." *Id*. § 101.9(c)(6)(iii). As implemented, the nutrition label required by the FDA's regulations appears as follows:

Nutrition Facts

8 servings per container
Serving size **2/3 cup (55g)**

Amount per serving
Calories **230**

	% Daily Value*
Total Fat 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
Includes 10g Added Sugars	**20%**
Protein 3g	
Vitamin D 2mcg	10%
Calcium 260mg	20%
Iron 8mg	45%
Potassium 240mg	6%

* 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.

Dkt. 23-1 at 15. As can be seen in this example, food products must declare how many grams of added sugars are contained in each serving of the food product, as well as the percent daily value that this amount of added sugar represents in the recommended daily diet for an American adult.

The percent daily value is a figure that "provides information that Americans can use to determine how the amount of added sugars" or another nutrient "in a serving of food contributes to his or her individual total daily diet." Added Sugar Final Rule, 81 Fed. Reg. at 33800. It is calculated by dividing the weight of the nutrient in a serving size of the food by the daily reference value for that nutrient. For added sugar, the daily reference value ("DRV") (also known as the "reference daily intake" or "RDI") for adults is 50 grams. 21 C.F.R. § 101.9(c)(9).

In the same rulemaking that introduced the added-sugar declaration to the nutrition label, the FDA also considered whether it should change the way that "carbohydrate" is defined, that is "whether carbohydrates should be classified and declared in nutrition labeling based on their chemical definition (which is the current method) or on their physiological effect (e.g., attenuation of blood sugar or laxation)." Added Sugar Final Rule, 81 Fed. Reg. at 33795. A

sugar is a carbohydrate, and accordingly, the "total sugar" and "added sugar" declarations appear as subheadings under the "total carbohydrate" heading. After soliciting comments on the topic, the FDA decided not to change the way it defined carbohydrates in its 2016 rulemaking. As the FDA explained:

> Carbohydrates include starch, sugars, sugar alcohols, and dietary fibers and different carbohydrates have different physiological effects. Within the different types of carbohydrate (i.e., starch, sugars, sugar alcohols, and dietary fibers), too, specific carbohydrates may have different physiological effects (e.g., different types of dietary fibers) making it difficult to apply a definition that is based on physiological effects across a category of carbohydrates. Furthermore, analytical methods for measuring different types of carbohydrates are based on chemical structure rather than physiological effect. Given the various components of total carbohydrate and different types of physiological effects of each, we decided not to change our provisions for the classification or declaration of carbohydrates specified in § 101.9(c)(6).

Id. (internal citations omitted).

In reaching that conclusion, the FDA noted that it had received several comments about different sugars in particular. Some commentators requested that tagatose and another sugar alternative, isomaltulose, be reclassified and exempt from the added sugar regulations because of their "effect on reducing the risk of dental carries" and the "reduced blood glucose response" they induce after consumption. *Id.* at 33837. The FDA responded that:

> We have recognized through our health claim for noncariogenic carbohydrate sweeteners and dental caries that the sugars D-tagatose and isomaltulose may reduce the risk of dental caries (tooth decay). However, D-tagatose and isomaltulose are chemically sugars. Because these sweeteners are chemically sugars, and other substances are included or excluded from the definition of sugars and added sugars based on whether they are a free mono or disaccharide rather than on their physiological effects, including D-tagatose and isomaltulose is consistent with how we have characterized other sugars. As such, we are not excluding D-tagatose and isomaltulose from the added sugars declaration.

Id.

Other commentators requested that allulose (also known as psicose), "a monosaccharide that is derived from fructose," be exempted from both the carbohydrate and sugar declarations. *Id.* at 33795. "According to th[ose] comments, Allulose is approximately 70 percent as sweet as sucrose, but contributes less than 0.2 calories/gram to the diet." *Id.* In addition, "[t]he comments suggested that Allulose does not have the metabolic properties of fructose or other sugars and does not contribute calories or raise blood sugar levels like other sugars do." *Id.* In light of these differences, the commenters requested that allulose be exempted from the definition of a carbohydrate. In response, the FDA stated that allulose "as a monosaccharide must be included in the declaration[s]." *Id.* at 33796. But, at the same time, the FDA noted (1) that it had received a citizen petition from a manufacturer of allulose, Tate & Lyle Ingredients Americas LLC ("Tate & Lyle"), requesting that the substance be exempted from various labeling requirements and (2) that the agency was reviewing "the information provided in the comments and the citizen petition." *Id.*

1. *Allulose Exception*

Approximately four years later, the FDA rendered a decision on the Tate & Lyle petition and issued guidance concerning the treatment of allulose on nutrition labels. In a notice published in the Federal Register on October 19, 2020, the agency declared its intent to "exercise enforcement discretion for the exclusion of allulose from the amount of Total Sugars and Added Sugars declared on the label." *See* The Declaration of Allulose and Calories from Allulose on Nutrition and Supplement Facts Labels, 85 Fed. Reg. 66217, 66218 (Oct. 19, 2020) (hereafter "Allulose Notice"). In addition, the FDA determined that food manufacturers could calculate the total calories in products containing allulose using a lower caloric value for each gram of allulose

in the food item. Instead of the 4 kcal/gram figure used for traditional sugars, food producers could use a 0.4 kcal/gram figure for allulose. *Id.*

The FDA explained that it had decided to "exercise enforcement discretion with respect to the exclusion of allulose from the amount of Total Sugars" because allulose varied from traditional sugars in several key respects. Dkt. 37-5 at 86. Traditionally, the agency had "determined what is captured under the Total Sugars declaration on the label by chemical structure," but "[d]ue to advances in food technology," the agency recognized that "novel sugars are now available that are not metabolized and that do not contribute 4 kcal/g to the diet like other traditional sugars." *Id.* at 84. Accordingly, the FDA stated that:

> [Its] current thinking is that, consistent with the goal of section 403(q) of the Federal Food, Drug, and Cosmetic Act for the nutrient declarations to assist consumers in maintaining healthy dietary practices, [the agency] should consider not only the chemical structure of sugars, but also other evidence, including their association with dental caries and how they are metabolized in the body (e.g., caloric contribution and their effect on blood glucose and insulin levels), when determining whether a sugar should be included in the declaration of Total Sugars on the label.

Id. The agency then elaborated on several of those non-chemical traits that traditional sugars possess but that alternative sugars may not similarly possess, and it identified three "important considerations [to apply] when determining whether a sugar should be excluded from the Total Sugar declaration," *id.* at 84-85:

First, the FDA observed that sugars "are known to be associated with increased risk of dental caries" because "[s]ugars that are metabolized by oral bacteria produce polymers that adhere to the tooth surface (i.e., dental plaque) and generate acids resulting in a decrease in the pH of dental plaque," which "provides an environment that allows for decalcification of the teeth." *Id.* at 84–85. Therefore, the agency stated that "evidence related to the association between the consumption of a sugar and dental caries is an important consideration when

determining whether the amount of a particular sugar in a serving of a product should be excluded from the Total Sugars declaration." *Id.* at 85.

Second, it observed that disaccharides typically provide 4 kcal per gram. Therefore, "[i]f a consumer wishes to determine how many calories are contributed by sugars in their diet, they can multiply the grams of Total Sugars per serving by 4 kcal/g." *Id.* But because "manufacturers are substituting sugars that provide much less than 4 kcal/g," "[i]ncluding sugars that contribute much less than 4 kcal/g to the diet in the Total Sugars declaration would not accurately reflect the caloric contribution to the diet of sugars . . . that contain much less than 4 kcal/g." *Id.* Accordingly, the agency found "the caloric contribution of a sugar to be an important consideration when determining if the sugar should be excluded from the amount of the Total Sugars declaration." *Id.*

Third, the agency observed that "[c]onsuming sugar increases circulating glucose in the blood stream," which, in turn, "triggers the release of the hormone insulin from the pancreas." *Id.* It further explained that "[t]he Total Sugars declaration provides consumers with information that they can use to determine whether a product contains sugars that are likely to cause an increase in circulating blood glucose and insulin levels," *id*., which, as Tate & Lyle stressed, is especially important for those consumers who have diabetes, Dkt. 37-3 at 97 (consumers with diabetes rely "heavily on the Nutritional Fact panel to assist in their treatment plan which includes dietary and in some cases medication"); *id.* at 103 ("[C]onfusion within this population with diabetes is of significance as it could result in individuals using insulin or medication to control diabetes to either avoid this product or to administer insulin or other medication prior to consuming the product."). Because "[s]ome consumers expect that when they eat sugars, the result will be an increase in blood glucose and insulin levels," the FDA concluded that "a sugar's

effect on blood glucose and insulin levels [are] important considerations when determining whether a sugar should be excluded from the Total Sugars declaration." Dkt. 37-5 at 85.

Considering all three of these "important considerations" as applied to allulose, the FDA determined that allulose should not be considered an equivalent to a traditional sugar for nutrition labeling purposes:

> [1] As previously discussed, allulose does not result in a decrease in the dental plaque pH below 5.7, at which decalcification of dental enamel may begin, and thus, does not promote dental caries. [2] It provides much less than 4 kcal/g. [3] Additionally, the consumption of allulose produces only a negligible increase in glycemic and insulinemic responses. Therefore, we intend to exercise enforcement discretion with respect to the exclusion of allulose from the amount of Total Sugars.

Id. at 86. And because the "added sugars" declaration is a subset of the "total sugars" declaration, the FDA concluded that it would not consider allulose to be an added sugar. *Id.* Finally, the agency determined that it would permit food producers to use a lower caloric value for allulose than for traditional sugars in calculating the "total calories" figure on the nutrition label. *Id.* at 82 ("Based on [the FDA's] review of the evidence, [it] conclude[d] that the caloric contribution of allulose is very low (i.e., no more than 0.4 kcal/g) because the majority of allulose is excreted intact in the urine, and because allulose is poorly fermented in the gut.").

2. *Tagatose Petition*

On April 18, 2018, Bonumose submitted a petition of its own in which it asked the FDA to treat tagatose differently than traditional sugars. Dkt. 37-2 at 76. Specifically, Bonumose "request[ed] [that the FDA] exempt D-tagatose from its classification as an added sugar on the Nutrition Facts Panel on foods and beverages (21 C.F.R. § 101.9(c)(6)(iii)) and amend the regulation to include a voluntary labeling of D-tagatose, similar to that which is provided for

sugar alcohols (21 C.F.R. § 101.9(c)(6)(iv))." *Id.* at 77. Bonumose argued that these actions were warranted because:

> 1. D-tagatose does not increase risk for chronic disease. Instead, it is associated with a number of positive health outcomes including an increase in glycemic control, reduction in risk for tooth decay, function as a prebiotic, and reduction in risk for cardiovascular disease (CVD).
>
> 2. Inconsistent methodology has been used to define added sugars and regulate their labeling.
>
> 3. Classification of D-tagatose as an added sugar conflicts with FDA rationale regarding the purpose of mandatory added sugar labeling.
>
> 4. Classification of D-tagatose as an added sugar is misrepresentative because there is no evidence supporting a link between D-tagatose and chronic disease. It also results in an inaccurate label that could confuse consumers.
>
> 5. Classification of D-tagatose as an added sugar contradicts the spirit of recognized health claims.

Id. In support of its claims about tagatose and its health effects, Bonumose provided several dozen scientific publications and additional authorities. *Id.* at 80–84.

On May 18, 2022, the FDA rejected Bonumose's petition, refusing to take both of the actions that Bonumose had requested. Dkt. 37-2 at 186. After describing the relevant background, *id.* at 186-189, the agency provided the following responses to some, but not all, of Bonumose's arguments:

First, the agency addressed Bonumose's argument that tagatose "is associated with numerous health benefits and does not share similar metabolic and physiologic characteristics with traditional sugars." Dkt. 37-2 at 189. The agency wrote: "While we have recognized through our health claim for dietary noncarcinogenic carbohydrate sweeteners and dental caries that D-tagatose *may reduce the risk of dental caries* . . . , as described below, the caloric

contribution from D-tagatose was not relevant to that determination, but is the basis for our decision here." *Id.* (emphasis added).

Next, the agency addressed Bonumose's assertion that "classification of D-tagatose as an added sugar conflicts with [the FDA's] rationale regarding the purpose of mandatory added sugar labeling." *Id.* The agency disagreed, again focusing exclusively on the caloric contribution from tagatose:

> As previously noted, we have considered the presence of added sugars as a component of dietary intake and whether it contributes empty calories to the diet. Your petition states that the caloric contribution of D-tagatose is 1.5 kcal/g (petition at page 10), which is significantly higher than allulose. Your petition also refers to [General Recognized as Safe ("GRAS")] notices for D-tagatose . . . , which further describe use levels for D-tagatose in foods. Those use levels indicate that the amount of empty calories to the diet provided by D-tagatose could be significantly greater than the amount provided by, for example, allulose or non-nutritive sweeteners. As described above, we have stated that small amounts of added sugars can add up throughout the day and contribute to the diet in a way that makes it difficult to meet nutrient needs within calorie limits. Therefore, we disagree that classification of D-tagatose as an added sugar conflicts with our rationale regarding the purpose of mandatory added sugar labeling.

Id.

Third, the FDA disagreed with Bonumose's contention that the agency had "used inconsistent methodology to define 'Added Sugars' and [to] regulate their labeling." *Id.* The agency wrote:

> [O]ur regulations . . . defined "sugars," and now define "Total Sugars," as the sum of all free mono- and disaccharides. We recognize that our regulations did not define "Added Sugars" before we published our Nutrition Facts final rule in 2016. However, with the finalization of that rule, our regulations, at § 101.9(c)(6)(iii), specify that "Added Sugars" are either added during the processing of foods, or are packaged as such, and include, among other things, sugars (free, mono and disaccharides).

Id. And, as the agency further explained, its "regulations . . . specify the conditions under which the terms 'no added sugar,' 'without added sugar,' and 'no sugar added' may be used." *Id.* at 189-190.

Finally, the FDA addressed allulose and explained that, since receiving the allulose petition in 2015, the agency had "received additional petitions and comments from stakeholders regarding the nutritional labeling of sugars that may be metabolized differently than traditional sugars." *Id.* at 190. In response, the agency issued a request for information and, "[b]ased on the evidence that [it] reviewed," it concluded that "these sugars are not necessarily identical such that [it] could consider treating them identically for purposes of nutritional labeling." *Id.* Thus, "while allulose provides no more than 0.4 kcal/g," tagatose "provides approximately 1.5 kcal/g." *Id.* For this reason, and in light of "the potential prevalence in the diet of D-tagatose, the total caloric contribution from sugars such as allulose and D-tagatose could differ significantly." *Id.* The agency then concluded that although it "issued an enforcement discretion guidance regarding allulose's inclusion in the Added Sugars declaration," it was unprepared "to amend [the added sugars] regulations regarding the declaration of D-tagatose on Nutritional Facts labels at this time." *Id.*

Although the FDA denied Bonumose's citizen petition to the extent it sought "to exempt D-Tagatose from its classification as an added sugar on the Nutrition Facts Panel on foods and beverages," the agency indicated that it "would not object to the use of 1.5 calories per gram (kcal/g) for D-tagatose when determining 'Calories' on Nutrition and Supplement Facts labels." *Id.* at 186 (footnote omitted); *see also id*. at 192.

In a subsequent decision issued on December 13, 2023, the FDA also acknowledged that "[t]he %DV declaration for products containing D-tagatose is calculated using an added sugars

Daily Reference Value, which is based on a standard calorie per gram value of 4 kcal/g for carbohydrates," but that "the caloric contribution of D-tagatose . . . is 1.5 kcal/g." Dkt. 37-6 at 384–85. The agency, accordingly, stated that it "intend[ed] to exercise enforcement discretion if the %DV calculation in the 'Added Sugars' declaration on the Nutrition Facts label for products containing D-tagatose is adjusted based on the caloric contribution of D-tagatose, which is 1.5 kcal/g."[2] *Id.* at 385.

B. Procedural History

Bonumose filed this suit on March 8, 2023, challenging the FDA's decision to deny its tagatose petition and challenging the constitutionality of 21 C.F.R. § 101.9(c)(6)(iii) as applied to food products that contain tagatose. Dkt. 1 (Compl.); Dkt. 19 (Am. Compl.). On August 25, 2023, Bonumose moved for summary judgment on both claims, Dkt. 23, and on September 29, 2023, the FDA moved to dismiss Bonumose's First Amendment challenge for lack of standing, and cross-moved for summary judgment on both claims, Dkt. 25; Dkt. 26. Bonumose filed the Joint Appendix on January 16, 2024, Dkt. 37, and the Court heard oral argument on July 12, 2024, Min. Order (July 12, 2024). Subsequently, the parties supplemented the Joint Appendix. Dkt. 43. Finally, Bonumose has sought leave to file a supplemental brief and declaration addressing its standing to bring a First Amendment challenge, Dkt. 44, and the parties have

[2] Both the Tate & Lyle (allulose) and the Bonumose (tagatose) citizen petitions asked the FDA to amend the governing regulations, *see* Dkt. 37-3 at 94 (allulose petition); Dkt. 37-2 at 77 (tagatose petition), and, in both cases, the FDA declined to do so and, instead, exercised its enforcement discretion. With respect to the Tate & Lyle petition, the agency exercised that discretion to exclude allulose from the Total Sugars and Added Sugars declarations, Dkt. 37-5 at 86–87, and, with respect to the Bonumose petition, the agency declined to exempt tagatose but did exercise its enforcement discretion to permit the use of the 1.5 kcal/g caloric contribution in lieu of the standard 4.0 kcal/g contribution, Dkt. 37-2 at 186.

jointly requested that the Court set a schedule—extending into late September—for further briefing on that question. Dkt. 45.

Thus, as the case currently stands, the parties' cross-motions for summary judgment are ripe for decision, while they have requested time for further briefing regarding Bonumose's First Amendment standing.

II. LEGAL STANDARD

Summary judgment is appropriate under Federal Rule of Civil Procedure 56 when the pleadings and the evidence demonstrate that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "In a case involving review of a final agency action under the [APA], however, the standard set forth in Rule 56(a) does not apply because of the limited role of a court in reviewing the administrative record." *Kadi v. Geithner*, 42 F. Supp. 3d 1, 8 (D.D.C. 2012) (citation omitted). In the unique context of a case brought under the APA, the district court "sit[s] as an appellate tribunal," *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1222–23 (D.C. Cir. 1993), to decide "as a matter of law [whether] the agency action is supported by the administrative record and is otherwise consistent with the APA standard of review," *Coal. for Common Sense in Gov't Procurement v. United States*, 821 F. Supp. 2d 275, 280 (D.D.C. 2011).

"When it comes to standing, however, district courts are not limited to the administrative record." *Ctr. for Biological Diversity v. Regan*, 597 F. Supp. 3d 173, 187 (D.D.C. 2022). A "plaintiff bears the burden of . . . establishing the elements of standing," and each element "must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015) (citation and quotation marks

omitted). When a defendant moves for summary judgment on the issue of standing, it must demonstrate "that there is no genuine dispute as to any material fact," Fed. R. Civ. P. 56(a), and that the plaintiff cannot establish the required elements of Article III standing based on the undisputed evidence, *see Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). The plaintiff may not rest on the mere allegations of the complaint but must, instead, "cit[e] to particular parts of materials in the record," Fed. R. Civ. P. 56(c), that demonstrate the existence of "a concrete and particularized 'injury in fact' that is fairly traceable to the challenged action of the defendant and likely to be redressed by a favorable judicial decision," *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 572 U.S. 118, 125 (2014) (citation omitted). "The evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986) (citing *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158–59 (1970)).

III. ANALYSIS

A. APA Claim

The Court's analysis begins and—at least for now—ends with Bonumose's APA claim. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency action will normally be set aside as "arbitrary and capricious" if the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The "scope of

review under the 'arbitrary and capricious' standard," however, "is narrow." *State Farm*, 463 U.S. at 43. The Court must not "substitute its judgment for that of the agency," *id.*, but rather must ensure that "the process by which [an agency] reaches [its] result [is] logical and rational," *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374 (1998). "[S]o long as the agency 'examined the relevant data and articulated a satisfactory explanation for its action, including a rational connection between the facts found and the choice made,'" "[t]he court will ordinarily uphold [the] agency's decision." *Animal Legal Def. Fund v. Perdue*, 872 F.3d 602, 611 (D.C. Cir. 2017) (alterations omitted) (quoting *State Farm*, 463 U.S. at 43).

Bonumose's APA claim challenges the FDA's decision to deny the company's petition to exempt tagatose from the labeling requirements for added sugars. Bonumose argues that the FDA's decision was arbitrary and capricious because the agency failed to provide a satisfactory explanation for the denial. Most significantly, in the company's view, the FDA failed to reconcile its decision to deny the tagatose petition with its prior decision to grant the allulose petition, and therefore "depart[ed] from agency precedent without explanation." *Ramaprakash v. FAA*, 346 F.3d 1121, 1124 (D.C. Cir. 2003).

1.

The Court pauses at the outset to consider two threshold issues, neither of which the FDA invokes in its opposition or cross-motion: First, the FDA does not argue that Bonumose's APA challenge fails for lack of a reviewable, final agency action. *See* 5 U.S.C. § 704 (limiting judicial review under the APA to "final agency action[s] for which there is no other adequate remedy in a court"); *MediNatura, Inc. v. Food & Drug Admin.*, 496 F. Supp. 3d 416, 436 (D.D.C. 2020) (explaining that an agency action is final if the action "mark[s] the consummation of the agency's decisionmaking process" and the action determines the rights or obligations or parties

or legal consequences flow from the action (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). Second, the agency does not contend that the tagatose denial letter is unreviewable because it constitutes an exercise of agency enforcement discretion. *See* 5 U.S.C. § 701(a)(2) (precluding review "agency action [that] is committed to agency discretion by law"); *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (holding that an agency's decision not to institute enforcement proceedings in a given case is "presumptively unreviewable"). To the contrary, the agency disavowed both arguments at the hearing on the parties' cross-motions for summary judgment. *See* Dkt. 39 at 43–44.

Regarding the first of these issues, the absence of a final agency action constitutes a defense to an APA claim, but it is not a jurisdictional hurdle to review. *See Trudeau v. FTC*, 456 F.3d 178, 185–86 (D.C. Cir. 2006). The defense, therefore, is waivable, and the FDA's failure to raise it means that it is conceded. But even so, there are persuasive reasons to treat the FDA's rejection of Bonumose's citizen petition as a final agency action: the decision (along with the reconsideration decision) represents the culmination of the decision-making process concerning the tagatose petition. And the FDA does not dispute that legal consequences flow from the decision: tagatose-containing products may display a different caloric value than required by the regulation because of the denial letter, but tagatose otherwise remains classified as an added sugar for purposes of the Nutrition Facts label. Dkt. 37-2 at 186. The FDA, moreover, does not contest that had it granted the relief requested, those marketing products containing tagatose could have done so without listing tagatose as an added sugar on the label.

The second issue—that is, whether the decision constitutes an unreviewable exercise of agency enforcement discretion—raises a closer question, albeit one that the FDA does not raise as a defense. On one hand, the APA precludes judicial review of "agency action [that] is

committed to agency discretion by law," 5 U.S.C. § 701(a)(2), and, more specifically, an agency's decision not to institute an enforcement action in a given case is "presumptively unreviewable," *Heckler v. Chaney*, 470 U.S. 821, 832 (1985). But, on the other hand, "[b]ecause the APA creates a basic presumption of judicial review [for] one suffering legal wrong because of agency action, . . . the Supreme Court has read the exception in § 701(a)(2) quote narrowly." *MediNatura, Inc.*, 496 F. Supp. 3d at 444 (citations and internal quotation marks omitted). Consistent with this presumption, the D.C. Circuit has observed that "an agency's statement of a general enforcement policy may be reviewable," *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994) (emphasis omitted), and it has applied that distinction at least once, *see OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 809 (D.C. Cir. 1998) (holding that "an agency's adoption of a general enforcement policy is subject to review").

Here, the FDA's decision denying Bonumose's petition is best understood as a "statement of a general enforcement policy" applicable to all market participants, and the FDA does not argue to the contrary. The decision rejected Bonumose's request to amend the relevant regulation, although the agency agreed to "exercise enforcement discretion" to permit the use of Nutrition Facts labels that adjusts the percent Daily Value for products containing tagatose based on the 1.5 kcal/g caloric contribution. *See* Dkt. 37-6 at 385. Nothing in the FDA's letters indicates that its decision in limited to Bonumose, Dkt. 37-2 at 186-192, and the company's citizen petition sought relief with respect to the product, in general, and not the company, in particular, Dkt. 37-2 at 77. Indeed, the company explained that it is "a food ingredient manufacturer" that supplies tagatose to "food and beverage manufacturers." *Id.* And, as the FDA argues in its motion to dismiss, "as a bulk-ingredient producer," the company is not itself responsible for complying with the labeling requirement. Considered in this light, the denial

letter is best understood as a statement of a general enforcement policy that is applicable to any company that is required to label tagatose-containing foods and as a refusal to amend the governing regulation to include an exception that, on Bonumose's telling, is required to comply with the purposes of the FDCA and to maintain consistency in application of the law.

The Court also notes that, in defending this action, the FDA does not appear to place any weight on the fact that Tate & Lyle and Bonumose framed their respective citizen petitions as requests to amend the governing regulations, while the agency responded by treating the petitions as requests either to amend the regulations or to exercise enforcement discretion. *See supra* n.2. That approach, moreover, is consistent with Bonumose's May 21, 2020 submission to the FDA, which reiterated the company's request that the FDA "exempt tagatose from its classification as 'sugar' on the Nutrition Facts label," and, in doing so, invoked a recently promulgated Executive Order directing agency's consider, among other things, "'exercising appropriate *temporary enforcement discretion*.'" Dkt. 37-3 at 23–24 (emphasis in original). Either way, and in the absence of any argument from the FDA to the contrary, the Court is persuaded that the FDA's decision denying Bonumose's citizen petition is reviewable under the APA.

2.

Turning to the merits, Bonumose is correct that an agency cannot depart from prior precedent or change its policies without acknowledging that the agency is making such a change and offering a reasoned basis for doing so. As the D.C. Circuit has explained, although "[a]gencies are free to change course as their expertise and experience may suggest or require, . . . when they do so they must provide a 'reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.'" *Ramaprakash*, 346 F.3d. at

1124–25 (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 852 (D.C. Cir. 1970)). The agency "must, in short, explain why it has changed its policy." *CBS Corp. v. FCC*, 785 F.3d 699, 708 (D.C. Cir. 2015). If it fails to do so, that is, if it "fail[s] to come to grips with conflicting precedent," the agency has "inexecusabl[y] depart[ed] from [an] essential requirement of reasoned decision making,'" *Ramaprakash*, 346 F.3d at 1124 (quoting *Columbia Broad. Sys. v. FCC*, 454 F.2d 1018, 1027 (D.C. Cir. 1971)), and has acted arbitrarily and capriciously, *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1090 (D.C. Cir. 2009). Here, Bonumose argues that the FDA impermissibly departed from its decision granting the allulose petition when it decided to deny the tagatose petition.

As noted above, when the FDA granted the allulose petition, it acknowledged that the Final Added Sugars rule was premised on the "traditional[]" view that "what is captured under the Total Sugars" and Added Sugars declarations is "determined . . . by chemical structure." Dkt. 37-5 at 84. But the agency further explained that "[d]ue to advances in food technology, novel sugars are now available that are not metabolized and that do not contribute 4 kcal/g to the diet like other traditional sugars." *Id.* As a result, the FDA reconsidered its position that chemical structure was the only relevant factor in determining whether a substance should be classified as a "sugar" on nutrition labels.

The agency's new position, its "current thinking" on the issue, was the following:

> Consistent with the goal of section 403(q) of the Federal Food, Drug, and Cosmetic Act for the nutrient declarations to assist consumers in maintaining healthy dietary practices, we should consider not only the chemical structure of sugars, but also other evidence including their association with [1] dental caries and how they are metabolized in the body (e.g., [2] caloric contribution and their [3] effect on blood glucose and insulin levels), when determining whether a sugar should be included in the declaration [as a "sugar"].

Id. In explaining this new position, the FDA characterized each of these physiologic effects—that is, (1) dental caries, (2) caloric contribution, and (3) effect on blood glucose and insulin levels—as "important considerations," and it did not rank one effect as more (or less) important than the other two. *Id.* at 85.

Consistent with this new approach to classifying sugars, the agency applied each of these considerations to allulose when it resolved the Tate & Lyle petition. The FDA concluded that all three weighed in favor of exempting allulose from the added sugar declaration: (1) allulose has a lower caloric value than traditional sugars; (2) it is not associated with dental caries; and (3) consumption of allulose does not materially raise blood glucose levels. Under the traditional view, allulose was a "sugar" because it is a monosaccharide, but under the agency's new approach, allulose was not a "sugar." *Id.* at 85–86. The agency explained its reasoning as follows:

> [A]llulose does not result in a decrease in the dental plaque pH below 5.7, at which decalcification of dental enamel may begin, and thus, does not promote dental caries. It provides much less than 4 kcal/g. Additionally, the consumption of allulose produces only a negligible increase in glycemic and insulinemic responses. Therefore, we intend to exercise enforcement discretion with respect to the exclusion of allulose from the amount of Total Sugars declared on the label pending future rulemaking regarding amending the definition of Total Sugars.

Id. at 86.

Bonumose claims that tagatose has those same three features: (1) it provides a caloric contribution (1.5 kcal/g) that is "much less than" the caloric contribution of traditional sugars (4.0 kcal/g); (2) it does not increase the risk of dental carries; and (3) it does not materially raise blood glucose or insulin levels. It follows, on Bonumose's view, that had the agency faithfully applied the standard it announced in the allulose decision, it would have reached a similar decision on Bonumose's petition and would have exempted tagatose from the added sugar

declaration. In other words, it was only because the agency departed from the standard set forth in the allulose decision that the agency reached a different decision with respect to tagatose. To be sure, the APA does not preclude an agency from changing course, nor are tagatose and allulose carbon copies of one another. But here, Bonumose continues, the FDA departed—without explanation—from its reasoning in the allulose decision, and it essentially adopted a new "empty calorie" standard for determining what is a "sugar." According to Bonumose, it is that unexplained departure that runs afoul of the APA. The Court agrees.

In denying the tagatose petition, the FDA stressed that its decision was based on its consideration of tagatose's caloric contribution. Dkt. 37-2 at 189. In particular, the agency was concerned about the combined effect of tagatose's caloric contribution (which, although significantly lower than traditional sugars, is significantly higher than allulose), its "potential prevalence in the diet," and about how this combined effect might add to the "empty calorie" problem that the added sugar declaration was intended to solve. *Id.* at 189–90. As the agency explained, "we have stated that small amounts of added sugars can add up throughout the day and contribute to the diet in a way that makes it difficult to meet nutrient needs within calorie limits." *Id.* at 189. The FDA, however, said very little about the other two of three "important considerations"—dental caries and circulating blood glucose and insulin levels—addressed in the allulose decision. Its analysis of those considerations was limited to the following brief passage:

> [Y]ou assert that D-tagatose is associated with numerous health benefits and does not share similar metabolic and physiologic characteristics with traditional sugars . . . . While we have recognized through our health claim for dietary noncariogenic carbohydrate sweeteners and dental caries that D-tagatose may reduce the risk of dental caries . . . , as described below, the caloric contribution from D-tagatose was not relevant to that determination, but is the basis for our decision here.

Dkt. 37-2 at 189 (internal citations omitted). As explained below, this passing mention of two of the three "important considerations" fails the test of reasoned—and reasonably explained—decisionmaking.

As an initial matter, this analysis simply glosses over the very first consideration raised in Bonumose's petition—the "positive health outcomes" involving "glycemic control" resulting from the use of tagatose. Dkt. 37-2 at 77. In the allulose decision, the FDA noted that "a sugar's effect on blood glucose and insulin levels" is an "important consideration[]" in "determining whether a sugar should be excluded from the Total Sugars declaration." Dkt. 37-5 at 85. Bonumose raised this same point in its petition. Dkt. 37-2 at 77. It submitted substantial support for this health benefit. *Id.* at 80–81. Yet, in rejecting Bonumose's petition, the agency simply jumped—with no analysis whatsoever—from the "numerous health benefits" asserted in the petition to the conclusion that, even if tagatose might "reduce the risk of dental caries," that fact would make no difference because "the caloric contribution from D-tagatose [is] not relevant to" reduction in dental caries, and what matters is caloric contribution. *Id.* at 189. In short, the agency's decision notes that Bonumose's petition argued that tagatose should not be treated as an added sugar because, among other things, it does not increase blood glucose or insulin levels, Dkt. 37-2 at 80-81, yet the decision simply ignores this issue.

The FDA's decision fares only slightly better when it comes to the second consideration raised in Bonumose's petition—the "positive health outcomes" relating to "reduction in risk of tooth decay." *Id.* at 77. To be sure, unlike the "important consideration" of glycemic levels, the FDA at least purports to address dental caries in "respon[ding]" to the petition. *Id.* at 189. But it is mere *ipse dixit* to assert that the company's reliance on dental caries is irrelevant because the risk of dental caries is unaffected by caloric contribution, and it is caloric contribution—rather

than the risk of dental caries—that "is the basis for our decision here." *Id.* at 189. The agency never explains *why* the reduction of the risk of tooth decay was an "important consideration" in the allulose decision but was irrelevant in the tagatose decision. Dkt. 37-5 at 85.

This is not to say that the agency was bound to analyze all three "important considerations" in its tagatose decision and that it was precluded from concluding, for example, that all three considerations must be satisfied before the agency will exclude a sugar from the Total Sugars declaration. Nor is the agency precluded from determining that the caloric contribution consideration is paramount, and the agency will grant an exclusion only when the caloric contribution is below a certain threshold or when it is unlikely that the relevant sugar will ever constitute a "prevalen[t]" portion of the public diet. Dkt. 37-2 at 190. But the agency failed to offer any such explanation, nor did it explain why control of glycemic levels (i.e., "circulating blood glucose and insulin levels," Dkt. 37-5 at 85) plays second fiddle to caloric contributions. *See Ramaprakash*, 346 F.3d at 1125 ("An agency's failure to come to grips with conflicting precedent constitutes 'an inexcusable departure from the essential requirement of reasoned decision making.'" (quoting *Columbia Broad. Sys.*, 454 F.2d at 1027)).

These omissions take on heightened importance when considered against the backdrop of the allulose decision. There, the agency offered a detailed analysis of all three factors. Dkt. 37-5 at 84–85. The FDA explained that "a sugar's effect on blood glucose and insulin levels" was an important consideration because the "Total Sugars" and "Added Sugars" declarations "provide[] consumers with information that they can use to determine whether a product contains sugars that are likely to cause an increase in circulating blood glucose and insulin levels." *Id.* at 85. "Some consumers," such as those with diabetes, "expect that when they eat sugars, the result will be an increase in blood glucose and insulin levels." *Id.* A sugar alternative's effect on those

levels was therefore a key part of the calculus when deciding whether a sugar alternative should be classified as a "sugar" on nutrition labels. *Id.* Nor did the FDA so much as suggest that one factor was dispositive, or that all three factors needed to weigh in favor of reclassification for a sugar alternative to be exempted from the sugar declarations. Instead, the agency applied all three factors to allulose, concluding that because allulose does not increase the risk of dental caries, has a low caloric value, and does not materially increase blood glucose or insulin levels, it was appropriate to exempt that sugar from the added sugar regulations. *Id.* at 86.

The Court is therefore persuaded that the FDA plowed significant new ground in its tagatose decision, either by departing from the standard set forth in the allulose decision or, perhaps, by adding a new limitation on the reach of that decision. The allulose decision is best read to reject the rigid test based on chemical structure alone and to require, instead, a holistic consideration of the three physiologic considerations. Understood in this way, the tagatose decision departed from that framework without explanation. *See Fox*, 556 U.S. at 515.

It is also possible, however, to read the allulose and tagatose decisions as a progression of refinements on the prior, exclusive focus on chemical structure. In the allulose decision, the FDA concluded that an exemption was warranted because all three physiologic considerations pointed in the same direction. The tagatose petition, at least arguably, presented a different question because, unlike in the case of allulose, the caloric contribution (at least arguably) did not support granting an exemption. But the problem with this alternative view is that the FDA never explained that it was adopting a caloric contribution hard stop. It never explained why the caloric contribution of allulose (0.4 kcal/g) was "much less than 4 kcal/g," Dkt. 37-5 at 85, but the caloric contribution of tagatose (1.5 kcal/g) was not. And, most significantly, it never explained why the difference in caloric contribution between allulose and tagatose presented

health consequences of sufficient magnitude to disregard the other health benefits of tagatose—that is, reduced risk of dental caries and improved glycemic control.

Thus, even if the agency did not depart from the allulose decision, its failure even to mention glycemic controls and failure to offer any meaningful analysis of dental caries, would run afoul of the APA's demand for a "cogent[] explain[ation]" of "why [the] agency has exercised its discretion in a given manner." *State Farm*, 463 U.S. at 48. Although the courts will "uphold a decision of less than ideal clarity if the agency's path may be discerned," *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974); *see also State Farm*, 463 U.S. at 43, here, the Court cannot reasonably discern the agency's "path." Among other things, the Court is left to guess whether the FDA adopted an "empty-calorie" rule, which precludes ever exempting a sugar that contribute calories in excess of the 0.4 kcal/gm amount at issue in the allulose decision; whether the agency had in mind some different limit and, if so, what that limit was and what the scientific or medical basis was for drawing the line at that amount; whether it, in fact, considered the other health benefits of tagatose and simply decided that they were insufficient and did not merit discussion; whether it departed from the allulose decision or merely intended to refine the standard set forth in that decision; whether future citizen petitions should address glycemic control and dental caries; and, most importantly, what scientific or public health considerations warranted the agency's singular focus on caloric contribution (at an amount "much less than" the 4.0 kcal/gm found in traditional sugar but above the 0.4 kcal/gm found in allulose, Dkt. 37-5 at 85) and failure to consider the effects of tagatose on dental caries or circulating blood glucose and insulin levels.

The closest the agency comes to justifying a change in position—or to explaining why it was refining that position or why the allulose standards were not met—appears in a passage in

the denial letter in which the agency acknowledges that, since the allulose petition, the agency has received numerous requests like the one Bonumose submitted, seeking to exempt sugar alternatives from the Added Sugars declaration. There, the agency states that:

> Since we received the 2015 allulose petition, we have received additional petitions and comments from stakeholders regarding the nutrition labeling of sugars that may be metabolized differently than traditional sugars. In response to the number of sugars that stakeholder comments and petitions claim have distinct characteristics from traditional sugars and to the wide scope of physiological and metabolic factors to consider, we requested more information on these types of sugars through our RFI. Based on the evidence that we have reviewed, these sugars are not necessarily identical such that we could consider treating them identically for purposes of nutrition labeling. For example, while allulose provides no more than 0.4 kcal/g, your petition states that D-tagatose provides approximately 1.5 kcal/g. Because of this and the potential prevalence in the diet of D-tagatose, the total caloric contribution from sugars such as allulose and D-tagatose could differ significantly. Thus, while we issued an enforcement discretion guidance regarding allulose's inclusion in the Added Sugars declaration, we declined at that time to amend our regulations to exempt allulose from the Added Sugars declaration because we wanted to further consider the issue in a potential future rulemaking. We are not prepared to amend our regulations regarding the declaration of D-tagatose on Nutrition Facts labels at this time.

Dkt. 37-2 at 190. But at no point in this passage does the FDA state that it is changing (or refining) its position from the one it expressed in its allulose decision or that tagatose fails to satisfy that standard. It does not, for example, state that due to the volume of requests and the importance of combatting the empty calorie problem, the agency's new focus will be on caloric value above all other physiological effects that a sugar alternative may have.

Nor does this passage refer to the statutory standard pursuant to which the FDA may make adjustments to what is required on nutrition labels. Under 21 U.S.C. § 343(q)(2), the FDA may, by regulation, change what is displayed on the nutrition label if doing so "will assist consumers in maintaining healthy dietary practices." When the FDA articulated its three-consideration standard in its allulose decision, the agency noted that it was departing from the

chemical-structure standard because doing so was "consistent with the goal of [§ 343(q)] for the nutrient declarations to assist consumers in maintaining healthy dietary practices." Dkt. 37-5 at 84. The FDA made no such finding in the tagatose decision, and, indeed, beyond noting that "consumers need to have information on the label so that they can consider the amount of added sugars in . . . foods . . . when constructing a healthy dietary pattern that contains less than 10 percent of calories from added sugar," Dkt. 37-2 at 187, the decision says little about that goal. Nor did the FDA grapple with the implications of its prior statements in the allulose petition concerning the importance of "provid[ing] consumers with information that they can use to determine whether a product contains sugars that are likely to cause an increase in circulating blood glucose and insulin levels," Dkt. 37-5 at 85, in a country in which approximately half of American adults have one or more preventable, chronic diseases related to poor dietary patterns, including diabetes, *see* DGAC Report 2015, at 38, https://perma.cc/4ABB-RGE7.

The Court, accordingly, concludes that the FDA acted arbitrarily and capriciously in denying Bomumose's citizen petition because it "'depart[ed] from a prior policy *sub silentio* or simply disregard rules that are still on the books,'" *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1089 (D.C. Cir. 2009) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)), and failed to offer cogent reasons for granting the allulose petition, while denying the tagatose petition, *see State Farm*, 463 U.S. at 48. [3]

The FDA offers two final responses. The agency first argues that it did consider tagatose's physiologic effects, "including Bonumose's argument that tagatose did not increase

[3] To the extent that the FDA's decision to move away from the chemical-structure standard for determining what should be classified as a "sugar" on the nutrition label modifies an existing regulation, the Court will leave it up to the FDA to determine whether, on remand, it is appropriate to codify such changes through notice-and-comment or whether a letter decision meets the agency's obligations under the APA.

the risk of chronic disease and might in fact reduce the risk of chronic disease." Dkt. 24 at 27. But for support, the agency cites only to an internal email sent by an FDA official to other FDA officials—rather than to the denial letter itself. *See id.* In that internal email, the FDA official noted that Bonumose's petition claimed that tagatose is not associated with an increased risk of chronic disease, but expressed the official's own view that this claim should not impact tagatose's classification as a sugar because the FDA's rationale for including added sugars on the nutrition label was the "empty calorie" problem rather than the effect that added sugars had on the risk of chronic disease. Dkt. 37-6 at 293. This email falls short of meeting the FDA's obligation to explain the basis for its decision in the decision itself. If an agency is going to reverse (or refine) a policy position, it must set forth its reasons for doing so; it cannot rely on the views expressed by one staffer during internal agency deliberations. *See Fox*, 556 U.S. at 515–16; *State Farm*, 463 U.S. at 43.

The FDA also argues that even though it did not address tagatose's metabolic effects in its denial letter, it was not required to do so. Dkt. 33 at 19, 21. Because "tagatose's caloric contribution was the dispositive factor," the FDA contends that it "did not need to reach [tagatose's] metabolic effects." *Id.* at 21. The problem that the FDA faces, however, is that this is not what it said in the decision letter. The closest the letter comes to expressing that view—and placing primary reliance on the caloric contribution consideration—comes in the following sentence: "While we have recognized through our health claim for dietary noncariogenic carbohydrate sweeteners and dental caries that D-tagatose may reduce the risk of dental caries, . . . the caloric contribution of D-tagatose was not relevant to that determination, but is the basis for our decision here." Dkt. 37-2 at 189. This sentence says nothing at all about "circulating blood glucose and insulin levels," Dkt. 37-5 at 85, and it offers no meaningful

analysis of the risk of dental caries. Instead, it merely asserts that "the basis for" the agency's decision is "caloric contribution." Dkt. 37-2 at 189. That proposition is both obvious and undisputed; the agency did base its decision solely on caloric contribution. But that does not resolve—or even touch upon—the questions that are dispositive for present purposes: *why* did the FDA rely exclusively on that factor to the exclusion of the two other "important considerations" addressed in the allulose decision, *what* scientific or public health evidence, if any, supports that departure or refinement from the allulose decision, and *what* level of caloric contribution crosses the line for purposes of characterization of a substance as an added sugar?

There may well be a good reasons for why the FDA relied exclusively on caloric contribution in its tagatose decision, but *ipse dixit* does not satisfy the APA.

B. Remedy

Having concluded that Bonumose is entitled to prevail on its APA claim, the Court is left with the question of the appropriate remedy. Ordinarily, upon finding that an agency action is unsupported, a court vacates the action and remands to the agency for further proceedings. *See Advocs. for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005) ("[U]unsupported agency action normally warrants vacatur."). Here, however, Bonumose asks this Court to go a step further and not only vacate the FDA's decision to deny its tagatose petition but to also order that the FDA affirmatively grant the petition. Such relief is inappropriate in an APA case in which the plaintiff prevails on the theory that the agency failed to explain the basis for its decision. To grant the relief that Bonumose seeks, the Court would have to substitute its judgment for that of the agency, which is the antithesis of arbitrary and capricious review. *State Farm*, 463 U.S. at 43. The Court will thus vacate the FDA's May 18,

2022 denial order concerning Bonumose's tagatose petition and will remand for further agency proceedings, but the Court will not compel the FDA to reach any conclusion on remand.

C. First Amendment Claim

There also remains the question of whether to the Court should rule on Bonumose's First Amendment claim. As a general matter, courts have long adhered to the principle that it is prudent to "avoid deciding constitutional questions presented unless essential to proper disposition of a case." *Dalton v. Specter*, 511 U.S. 462, 472 (1994) (quoting *Harmon v. Brucker*, 355 U.S. 579, 581 (1958)). Here, deciding the First Amendment claim is not essential to the disposition of this case because Bonumose may receive the relief it seeks on remand to the agency. The FDA may, after revisiting its decision, determine that a different course of action for tagatose is warranted, which could either moot the First Amendment claim or could change its contours. Moreover, to the extent that Bonumose believes that First Amendment considerations further support the relief that it seeks, it is free to raise those arguments on remand and, if necessary, in any subsequent judicial proceeding.

CONCLUSION

For the foregoing reasons, the Court will **GRANT** Bonumose's motion for summary judgment, Dkt. 23, with respect to its APA claim, will **DENY** FDA's cross-motion for summary judgment, Dkt. 25, on the same claim, and will **VACATE** and **REMAND** the FDA's May 18, 2022 denial order of Bonumose's tagatose petition for further proceedings consistent with this decision.

The Court will also **DENY** Bonumose's motion for summary judgment, Dkt. 23, with respect to the First Amendment claim, and will **DENY** FDA's cross-motion for summary judgment, Dkt. 25, with respect to the same claim as premature. The Court will **DENY** as **MOOT** Bonumose's motion for leave to supplement, Dkt. 44, and the parties' joint motion for extension of time to file a response or reply, Dkt. 45.

A separate order will issue.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: August 28, 2024