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FDA Finalizes Allulose Guidance and Requests Information on Other Sugars Metabolized Differently Than Traditional Sugars

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Food, Drug, and Device

FDA has taken two notable actions regarding the sugars declaration in the Nutrition Facts Label (NFL) and Supplement Facts Label (SFL). On Friday, the agency released a [final guidance](#) regarding the declaration of allulose, confirming that this monosaccharide need not be included in the declaration of “Total Sugars” or “Added Sugars,” though it must be included in the “Total Carbohydrates” declaration in the NFL. Today, FDA published a Federal Register [notice](#) requesting information about and comments on the nutrition labeling of other sugars that are metabolized differently than traditional sugars. We briefly summarize both documents below to help inform stakeholder comments on the notice, which are due to FDA by December 18, 2020.

Allulose Final Guidance

Allulose, or D-psicose, is a monosaccharide that can be used as a substitute for traditional sugar in food and beverage products. For purposes of nutrition labeling, FDA has generally defined nutrients based on their chemical structure.¹ Accordingly, when FDA updated its NFL and SFL regulations in 2016, the agency reiterated the definition of “Total Sugars” as the sum of all free monosaccharides and disaccharides (*e.g.* glucose, fructose, and sucrose).² FDA also added to these regulations a definition of “Added Sugars” – sugars added during the processing of food, or packaged as such – and required their declaration in the NFL and SFL.³ Although the agency recognized that there are sugars that are metabolized differently than traditional sugars, FDA did not make a determination at that time as to whether allulose should be excluded from “Total Carbohydrate,” “Total Sugars,” or “Added Sugars” Declarations. The agency also noted that D-tagatose and isomaltulose are chemically sugars and therefore not excluded from “Total Sugars” and “Added Sugars” calculations.

¹ FDA’s recent definition of “dietary fiber” was a notable departure from this approach. See, *e.g.*, our client alerts [here](#) and [here](#).

² 21 C.F.R. § 101.9(c)(6)(ii).

³ 21 C.F.R. § 101.9(c)(6)(iii).

FDA released a draft guidance on April 18, 2019, announcing it would exercise enforcement discretion to allow allulose to be excluded from the calculations of “Total Sugars” and “Added Sugars,” though the agency would require that allulose be included in the calculation of “Total Carbohydrates.” FDA also allowed the caloric contribution of allulose to be calculated as 0.4 calories per gram, rather than 4 calories per gram, as used for traditional sugars. In its final guidance, FDA confirmed this approach. In reaching these conclusions, FDA relied heavily on information and data submitted in citizen petitions and comments on the draft guidance and in FDA’s nutrition labeling rulemaking. FDA also relied on an independent review of scientific evidence on allulose. Specifically, the agency reviewed scientific data relating to metabolism, caloric value, glycemic response, and cariogenic potential and reached the following conclusions:

- **Caloric Value:** FDA concludes that the caloric contribution of allulose is very low and no more than 0.4 kcal/g. The agency therefore intends to exercise enforcement discretion for the use of 0.4 kcal/g as the caloric value for allulose, for purposes of calculating calorie declarations in nutrition labeling.
- **Total Carbohydrate:** FDA concludes that allulose must be included in the “Total Carbohydrate” calculation because it is a substance that is chemically a carbohydrate, and FDA previously determined that total carbohydrates should be based on chemical structure rather than physiological effect.
- **Total Sugars and Added Sugars:** FDA will allow allulose to be excluded from the “Total Sugars” and “Added Sugars” calculations. The agency concludes that, consistent with the purpose of nutrition labeling to help consumers maintain healthy dietary practices, it is appropriate to consider not only the chemical structure of sugars, but also other evidence relating to the effects of a particular sugar on the body. Specifically, FDA concludes that, unlike traditional sugars, allulose does not promote dental caries, negligibly increases glycemic and insulinemic responses, and is virtually unmetabolized in the body, and therefore should not be included in the sugars declarations in nutrition labeling.

FDA’s enforcement discretion will remain in place pending any rulemaking amending the agency’s nutrition labeling regulations with respect to allulose. FDA’s considerations in excluding allulose from the total and added sugars calculations, and allowing a lower caloric contribution than for other sugars, are instructive in considering comments about other sugars in response to FDA’s Federal Register notice discussed below.

FDA Request for Information on Sugars that Are Metabolized Differently Than Traditional Sugars

Now that FDA has issued its final guidance on allulose, the agency is seeking information about other sugars that are metabolized differently than traditional sugars, and is open to suggestions from interested stakeholders as to how it should treat these sugars for nutrition labeling purposes. FDA poses the following questions:

Key Elements of the Request

- **General Information on Sugar:** Other than allulose, D-tagatose, and isomaltulose, what other sugars are metabolized differently than traditional sugars? FDA requests that stakeholders provide studies and data on these sugars’ chemical properties and physiological effects. In addition, FDA wants any data on consumer awareness or understanding of these sugars.

- **Declaration of Total Sugars:** How should FDA account for these sugars in “Total Sugars”? Should they be counted, excluded, or adjusted based on caloric contribution? What factors should FDA consider in making its decision? For example, for allulose, FDA considered caloric value, glycemic response, and cariogenic potential. FDA asks that stakeholders provide any data or information to support such approach.
- **Declaration of Added Sugars:** How should FDA account for these sugars in “Added Sugars”? Should they be counted, excluded, or adjusted in the gram amount or %DV based on caloric contribution? What factors should FDA consider in making its decision? For example, for allulose, FDA considered glycemic and insulinemic responses and caloric value. FDA is also considering adjusting %DV calculations for these sugars based on caloric contribution. What considerations should FDA take into account in its calculations? FDA asks that stakeholders provide any data or information to support such approaches.
- **Label Declarations:** Should FDA allow voluntary declaration in the NFL of these sugars, as it allows for sugar alcohols? Should these other sugars be combined with sugar alcohols in one separate declaration on the label? If combined, what would be the appropriate name for their declaration on the label? FDA asks that stakeholders provide data and information to support these recommendations.

FDA’s determinations regarding other sugars will be based on the totality of available information and data provided by stakeholders and the scientific community. Interested stakeholders should therefore submit robust comments and data to the docket.

If you have any questions concerning the FDA updates discussed in this client alert, please contact the following members of our Food, Drug, and Device practice.

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**Andrew Do has not yet been admitted to the DC bar and is supervised by principals of the firm.*

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