

# FDA Announces Final Guidance on Nutrition and Supplement Facts Labels

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Food & Beverage

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Last Friday (November 2, 2018), FDA announced the availability of its final guidance, "[Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals: Guidance for Industry.](#)"

The guidance is in the form of a Q&A that presents FDA's position on the compliance dates and various technical issues related to calculating and rounding nutrients for declaration in the Nutrition Facts Label (NFL) and Supplement Facts Label (SFL). The bulk of the guidance (approximately 17 of 29 pages) conveys FDA's position on what constitutes added sugars and how to calculate added sugars in certain scenarios. With respect to calculating added sugars, the final guidance appears to provide flexibility for some of the technical issues that may arise in manufacturing and processing. This alert highlights some of the clarifications FDA provided regarding added sugars.

## **Added Sugars Do Not Include Certain Ingredients That Are Reconstituted to Single Strength or Akin to Whole Fruits and Vegetables**

FDA clarifies its position on fruit- and vegetable-based ingredients that are not added sugars and/or that would not need an added sugars declaration, including:

- Concentrated juice products made from 100 percent juice (e.g., frozen orange juice concentrate) sold directly to consumers that are typically reconstituted with water before consumption, that include directions for reconstituting the concentrated juice to 100 percent juice. FDA applies this same approach to fruit and vegetable juice powders that are sold to consumers in drink mixes and that provide directions to dilute the product to single-strength before consumption (FDA considers such powders akin to non-powdered 100 percent fruit or vegetable juices).
- Fruit or vegetable juice concentrates used towards the total juice percentage label declaration under 21 C.F.R. § 101.30, for Brix standardization under § 102.33(g)(2), to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in §§ 150.140 and 150.160, or the fruit component of fruit spreads.
- Whole fruits, fruit pieces, dried fruit, fruit or vegetable purees (single strength or concentrated), pulps, single strength juices, fruit and vegetable pastes, and fruit and vegetable powders that are not made from fruit or vegetable juices. FDA presumes such ingredients do not have any sugar added to them--any added sugars must be declared as added sugars.

- Vinegars that do not contain any sugars in the finished food (even if sugars were part of the fermentation process). Some vinegars, however, (e.g., balsamic vinegar) made using ingredients that are often used as sweeteners in foods, and that are similar to concentrated fruit juices (e.g., grape must) and have sugars that are in excess of what would be expected in the same volume of 100 percent fruit or vegetable juice of the same type, would need to declare the excess sugars as added sugars.

### **Added Sugars Do Include Maltodextrins and Other Ingredients**

In the final guidance, FDA retained its position that added sugars include sugars from maltodextrins, corn syrups, and other ingredients containing mono- and disaccharides created through controlled hydrolysis. Additionally, added sugars may include not only ingredients that meet FDA's definition of "added sugars" but also ingredients that may contain sugars that meet FDA's definition of "added sugars." FDA expects food manufacturers to work with their suppliers to determine the amount of free mono- and disaccharides in ingredients used in a food's formulation. Finally, FDA does not require the declaration of added sugars for products that contain less than 1 gram of added sugars per serving, so long as no claims are made about sweeteners (caloric or non-caloric), sugars, added sugars, or sugar alcohol content.

### **FDA Provides Flexibility in Calculating Added Sugars**

FDA does not prescribe how to calculate added sugars, but provides several examples for how to do so (see, e.g., Q&A's 8 – 12 for calculating added sugars in juice concentrates). FDA explains that the amount of added sugars is based on finished product composition. Given the potential variability and complexity associated food manufacturing and processing, FDA provides the following flexibility when calculating added sugars:

Use of all the moisture in the formulation (e.g., from milk, syrup, egg, diluted wines and cider with less than 7 percent alcohol by volume, etc.) to be counted towards reconstitution of concentrated juice. If initial juice ingredients in a formulation are further concentrated during processing due to loss of water (e.g., during drying or baking), FDA expects the calculation of added sugars to account for the loss of water during processing and to reflect the concentration of the juice ingredients after processing. Companies can use the moisture content of the finished product towards reconstitution of the juice soluble solids when the product is subject to water loss during processing.

If using FDA's Brix values to assess the sugars equivalent in 100% juice, FDA permits, consistent with its CGMPs, slight overages above the minimum Brix value, which overages would not need to be declared as "added sugars." If a product is designed to achieve higher Brix values above FDA's minimum Brix value for 100% juice (e.g., to increase sweetness) and the excess is above FDA's CGMP variations, the sugars in excess of 100% juice are "added sugars."

The final guidance also provides examples of how to calculate added sugars attributed from lactose (Q&A 15), in sweet fermented beverages (Q&A 17), and in products subject to non-enzymatic browning and/or fermentation (Q&A's 18 – 20), stating that in any case, the added sugars declaration should not exceed the total sugars declaration.

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