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MEMORANDUM

From: Martin J. Hahn
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Re: **FDA Issues Two Guidance Documents on New Nutrition Labeling Requirements**

The U.S. Food and Drug Administration (FDA) recently issued two guidance documents – one final and one draft – related to the new nutrition labeling requirements. The final guidance is an update to the previous draft guidance addressing the compliance date, added sugars definition, and quantitative declarations of vitamins and minerals.[1] The draft guidance is focused on the serving size, Reference Amounts Customarily Consumed (RACCs), and determining the appropriate Nutrition Facts Panel (NFP) format, including dual-column labeling. [2]

This memorandum summarizes the major highlights of the guidance documents, particularly where FDA has offered interpretations not found directly in the final rules. All food companies should consult FDA's new guidance documents as they continue to implement the new nutrition labeling requirements before the January 1, 2020 compliance date.

FDA's Final Guidance on Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals

Compliance Date

In the final guidance, FDA maintains its position that products "labeled" (i.e., when the label is placed on the product) on or after the compliance date must bear a NFP that meets the new nutrition

[1] 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, November 2018, *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535372.pdf.

[2] Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving-Size Related Issues, Dual-Column Labeling, and Miscellaneous Topics: Guidance for Industry, November 2018, *available at* https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM624571.pdf.

labeling requirements, but products labeled before the compliance date may use the old label.[3] FDA further explains that the mere presence of a product on a store shelf after the compliance date does not mean that the product is required to bear the new label, reinforcing that products labeled before the compliance date will continue to circulate in the marketplace after the January 1, 2020 compliance date (or January 1, 2021 for companies with less than $10 million in annual food sales) and will not be considered to be violative.

Added Sugars Definition

FDA's final guidance addresses a number of issues related to the added sugar definition, as applied to specific ingredients.

- FDA Recognizes Certain Fruit and Vegetable Ingredients Like Concentrated Purees Do Not Contribute Added Sugars.[4] The final guidance recognizes that fruit and vegetable ingredients like concentrated purees, fruit and vegetables pastes, and some fruit and vegetable powders, are more similar to the whole fruit or vegetable, and less similar to juice concentrates, and therefore are not to be considered added sugars. This is in contrast to FDA's previous position in the draft guidance, under which FDA took the position that removal of certain components found in the edible portion of the whole fruit or vegetable would result in the ingredient contributing to the added sugars declaration. FDA now recognizes that the peel or seeds can be removed from a fruit or vegetable ingredient without the ingredient being considered an added sugar. However, FDA states that sugars in powders made from fruits and vegetable juices are considered to be similar as sugar found in concentrated fruit and vegetable juices, and therefore, some or all of the sugars contributed by powder made from fruit or vegetable juices must be declared as added sugars on the Nutrition Facts label, depending on the degree of reconstitution in the finished food.

- FDA Acknowledges Brix Value is Minimum for Reconstituting Juices and Slight Overages, Consistent with Good Manufacturing Practices (GMPs), Are Not Considered Added Sugars. FDA's guidance acknowledges the industry practice of using the Brix value for 100% juice as a minimum when reconstituting fruit or vegetable juices, and that to ensure this Brix value is consistently met, manufacturers may target a slight overage of juice soluble contents above the Brix value for 100% juice. FDA explains that as long is the overage is consistent with GMPs, the overage would not need to be declared as added sugars, although if the overage is intended to achieve a higher juice soluble solids concentration than what is required by the minimum Brix value for 100% juice, such as to increase the sweetness of the product, FDA would expect the overage to be declared as added sugars.[5] FDA provides examples of how to perform these added sugar calculations in questions 10 and 11 of the guidance.

- Hydrolysis that Produces Sugars. FDA's final guidance states that "when an ingredient containing mono- and disaccharides that are created through controlled hydrolysis (e.g., maltodextrin or corn syrup) is added to a food during processing, those mono- and disaccharides contributed by the ingredients need to be declared as added sugars on the

[3] Final guidance at compliance date question 1.
[4] *Id.* at added sugars question 7.
[5] *Id.* at added sugars question 8.

label." [6] FDA's draft guidance previously suggested that such mono- and disaccharides contributed by hydrolyzed ingredients like maltodextrin need only be declared as added sugars when they contribute more than 0.5 g of sugar per serving to the finished product. The final guidance eliminates these statements and requires all of the sugars contributed by hydrolyzed ingredients to be declared as added sugars.

- Calculation of Added Sugars When There is Water Loss or Dilution During Processing. FDA provides examples of how to calculate the added sugars declaration when a fruit or vegetable juice ingredient is either diluted due to the addition of other water-containing ingredients or when water loss occurs during processing and the juice ingredient becomes concentrated (e.g., drying or baking).[7] FDA requires manufacturers to account for water loss when determining the added sugars declaration, but notes it would be appropriate to use the moisture content of the finished product towards reconstitution of the juice soluble solids when the product is subject to moisture loss during processing. The guidance provides a suggested approach for performing the calculations in this situation.

- Lactose. FDA's guidance explains that lactose, as a sugar inherent in a dairy product, is a disaccharide that is included in the total sugars declaration in the NFP, while purified lactose that meets the definition in 21 C.F.R. § 168.122 is captured in the NFP under both total and added sugars. The guidance recognizes that industry uses the enzyme lactase to hydrolyze lactose in dairy products for purposes of reducing the lactose content in low-lactose dairy products, and this hydrolysis results in the monosaccharides glucose and galactose. This hydrolysis, according to the agency, does not result in an increase in sugars that would affect the total sugars declaration. To the extent lactose that meets the standard of identity is hydrolyzed, FDA would expect the added sugars declaration to be the same before and after hydrolysis of lactose using lactase. Therefore, FDA does not consider the sugars created through the enzymatic hydrolysis of lactose, whether present as a component of a dairy product, a dairy ingredient, or contributed by the addition of lactose that meets the standard of identity to change the declarations for total or added sugars for the product.

Other Notable Issues

- Enforcement Discretion for Bottled Waters, Coffee Beans, and Certain Other Products Previously Exempt from Nutrition Labeling. Certain foods were historically exempt from mandatory nutrition labeling under 21 C.F.R. § 101.9(j)(4) because they had insignificant amounts of all nutrients required to be declared (e.g., bottled water products, coffee beans (whole or ground), tea leaves, plain unsweetened coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors). FDA intends to exercise enforcement discretion and refrain from taking regulatory or compliance actions against these products with respect to mandatory labeling if these products do not bear labels that meet the new requirements. FDA notes it intends to engage in future rulemaking to address issues of mandatory nutrition labeling of these products.[8]

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6 *Id.* at added sugars question 14.

7 *Id.* at added sugars question 12.

8 *Id.* at compliance date question 5.

- Rounding Rules for Quantitative Declarations of Vitamins and Minerals. FDA's final guidance maintains the same guidelines for rounding the quantitative declarations of vitamins and minerals in the NFP as the draft guidance.

FDA's Draft Guidance on Serving Sizes, RACCs, Dual-Column Labeling, and Miscellaneous Topics

FDA's draft guidance is a helpful resource for determining the serving size, number of servings, and appropriate NFP format for different types of food packages. A few notable issues FDA clarified in this guidance include:

- Enforcement Discretion To Label Foods That Qualify for Linear or Tabular NFP and Contain At Least 200% Up to and Including 300% of the RACC as a Single-Serving Container. In the draft serving size and Reference Amount Customarily Consumed (RACC) guidance, FDA clarifies that it will exercise enforcement discretion to allow products containing at least 200% up to and including 300% of the applicable RACC to be labeled as a single serving container, provided that it would not be misleading to do so, and that the product meets the requirement to use the tabular or linear NFP form. This enforcement discretion affords manufacturers flexibility to decide whether to label certain products in small packages as a single serving when the product does not meet the definition of a single-serving container, the package contains at least 200% and up to and including 300% of the RACC, and there is insufficient space to include two columns of nutrition information on the label.

- Bottom of Package Not Appropriate for Labeling. In the draft guidance, FDA notes that generally, the bottom of a package is not considered an appropriate principal display panel (PDP) or information panel, and the mandatory label elements should not be placed on the bottom of packages.

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We will continue to monitor FDA's implementation of the new nutrition labeling requirements. Please contact us if you have any questions or if you are interested in submitting comments on the new guidance documents.