COVINGTON

FDA Issues Draft Guidances on Nutrition Labeling

January 5, 2017

Food, Beverage, and Dietary Supplements

Yesterday, FDA issued a long-anticipated draft guidance intended to help industry comply with the agency's May 2016 final rules modernizing nutrition labeling.[1] Presented in a question-and-answer format, the draft guidance (Q&A Draft Guidance) provides information related to the compliance date, labeling of added sugars, rounding of the declaration of quantitative amounts of vitamins and minerals, and label format.[2] Notably, it does not address the issue of dietary fiber, which FDA defined for the first time in the new nutrition labeling regulations. Nor does it extend the current earliest compliance deadline of July 26, 2018.[3]

In addition, FDA released a draft guidance (RACC Draft Guidance) providing examples of foods that belong to each product category included in the tables of Reference Amounts Customarily Consumed (RACCs) per Eating Occasion that are established in FDA's serving size regulations.[4]

This alert highlights key aspects of these draft guidances and discusses issues on which industry stakeholders may wish to comment. Comments on the draft guidances should be submitted by March 6, 2017 (60 days after the date of publication).

Q&A Draft Guidance

The May 2016 revisions are the first major update to the nutrition label since it was originally required over 20 years ago. The final rules will result in a number of significant changes to Nutrition and Supplement Facts labels, including substantial changes to the "dietary fiber" declaration and a new "added sugars" declaration. Considerable uncertainty remains regarding these changes. The Q&A Draft Guidance seeks to address some, but not all, of the outstanding issues.

---

[1] *See FDA Issues Final Rules on Changes to Nutrition Labels*, Covington Client Alert (May 23, 2016), available here.
[2] Draft Guidance for Industry: Questions and Answers on the Nutrition and Supplement Facts Labels Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals (Jan. 2017), available here.
[3] This is the compliance date for manufacturers with $10 million or more in annual food sales. For manufacturers with less than $10 million in annual food sales, the compliance date is July 26, 2019.
[4] Draft Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category (Jan. 2017), available here.

Compliance Date

Although the Q&A Draft Guidance does not extend the current compliance timeframe, it clarifies that for purposes of determining the compliance date, FDA intends to consider the date the food product was *labeled*, regardless of the food's location in the distribution chain. In sum:

- Products that are labeled on or after July 26, 2018 (July 26, 2019 for manufacturers with less than $10 million in annual food sales) must bear a nutrition label that meets the new nutrition labeling requirements.
- Products that are labeled before July 26, 2018 (July 26, 2019 for manufacturers with less than $10 million in annual food sales) do not need to bear the new nutrition label.

Thus, manufacturers may continue to distribute products bearing the old nutrition labels after the compliance date, as long as they were labeled prior to that date. This guidance is much clearer than FDA's prior statement that the new label must appear on products that are "initially introduced into interstate commerce on or after the compliance date."

Labeling of Added Sugars

FDA dedicates a significant portion of the Q&A Draft Guidance to the topic of added sugars. The new nutrition label must declare the gram amount and percent Daily Value (DV) of "added sugars," which the final rule defines as "sugars [that] are either added during the processing of foods, or are packaged as such," including: sugars (free, mono- and disaccharides); sugars from syrups and honey; and sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type. The term "added sugars" does not include certain types of fruit or vegetable juice concentrates, nor does it include the fruit component of fruit spreads.

Thus, for the first time, manufacturers will need to calculate the amount of added sugars in their products. The Q&A Draft Guidance provides some much-needed guidance for industry regarding this calculation. Specifically, the draft guidance provides examples of methods industry may use to calculate the amount of added sugars in specific products, including sweet fermented beverages, baked goods in which sugar is added for fermentation, and fruit juice blends. It also address whether sugars in certain ingredients would be considered added sugars, as summarized below.

The Q&A Draft Guidance does not, however, address all the issues industry stakeholders have faced in grappling with this novel calculation. For example, it does not address whether certain novel sweeteners such as Allulose, a monosaccharide derived from fructose that contributes less than 0.2 calories/gram to the diet, will be excluded from the added sugars declaration.

<u>Treatment of fruits and vegetables that have been processed to change the form of the fruit or vegetable</u>

The Q&A Draft Guidance proposes the following approach to determine whether sugars found in fruits and vegetables that have been processed to change the form of the fruit or vegetable (e.g., concentrated fruit and vegetable purees, fruit and vegetable pastes, and fruit and vegetable powders) must be declared as added sugars on the label:

- If the ingredient contains all of the components of a whole fruit or vegetable, but has been processed so that the plant material is physically broken down into smaller pieces or water is removed, FDA would *not* consider the sugars contributed from the portion of

the fruit or vegetable that is typically eaten and which is used to make such an ingredient to be added sugars.

- If a fruit or vegetable is processed in such a way that it no longer contains all of the components of the portion of a whole fruit or vegetable that is typically eaten (e.g., the pulp from the fruit has been removed) *and* the sugars have been concentrated, FDA considers the sugars in such an ingredient to be consistent with how the agency has considered the sugars in fruit juice concentrate. FDA reached this conclusion because the ingredient is a concentrated source of sugars and contributes additional calories to a food when added as an ingredient without additional water. According to FDA, manufacturers should consider whether the ingredient has been processed so that, in addition to being concentrated, it no longer contains all of the components of the original portion of the whole fruit or vegetable that is typically eaten. If sugars are in excess of what would be expected from an ingredient made from 100% fruits or vegetables, those sugars must be declared as added sugars.

FDA's proposed approach does not expressly address how the agency would classify certain fruit or vegetable products, including: 100% fruit juice that is not concentrated but from which the pulp has been removed; and a whole fruit or vegetable that has been processed so that the plant material is physically broken down into smaller pieces *and* water has been removed (e.g., concentrated blueberry puree made from whole blueberries).

Treatment of ingredients containing sugars that are created through processes such as hydrolysis

Some ingredients contain mono- or disaccharides that are created through processes such as hydrolysis. Under the approach FDA proposes in the Q&A Draft Guidance, whether such sugars must be declared as added sugars on the label would depend, in part, on whether the sugars were produced intentionally. Sugars that are produced through incidental hydrolysis are not included in FDA's definition of added sugars, and would not be declared as added sugars on the label (but they would be captured in the total sugars declaration).

If a manufacturer purposely uses hydrolysis to increase the sugar content of a food product (e.g., enzymatic hydrolysis of corn starch to make corn syrup), FDA would consider the sugar generated from the hydrolysis step to be an added sugar, because hydrolysis was purposely used by the manufacturer to increase the sugar content of the product. Even so, the sugar may not need to be declared as added sugar on the label, depending on the level of such sugar present in the finished food product. The Q&A Draft Guidance does not expressly address a number of related issues, such as whether sugar specifically and purposely produced via hydrolysis must be declared as added sugar on the label if the finished product also contains other "added sugars."

The final rule requires manufacturers to make and keep written records of the amount of added sugars added to the food during processing, if the finished product contains both naturally-occurring and added sugars. Thus, these nuanced issues regarding processing of fruits or vegetables and processing methods such as hydrolysis mean that manufacturers must make careful records supporting their added sugars declaration, if not all sugars in the product are added sugars.

Claims about caloric and non-caloric "sweeteners" trigger the added sugars declaration requirement

Under the new nutrition labeling requirements, declaration of added sugars content is not required for products that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content. The Q&A Draft Guidance clarifies that because FDA traditionally has used the term "sweetener" to refer to ingredients that provide sweetness to a food regardless of whether they provide calories, the agency considers both caloric and non-caloric sweeteners—including sugar alcohols—to be sweeteners for the purposes of this regulation. Thus, if the label says "no artificial sweeteners," for example, then it also must declare the amount of added sugars in the product, even if that amount is less than 1 gram per serving.

Rounding of Quantitative Amounts of Vitamins and Minerals

The Q&A Draft Guidance addresses the final rule's ambiguity regarding the rounding of quantitative amounts of vitamins and minerals. For consistency, FDA recommends that manufacturers use the same principles for the declaration of quantitative amounts of vitamins and minerals on both the Nutrition and Supplement Facts labels. Those principles are summarized in the following chart:

Vitamins and Minerals with a Reference Daily Intake (RDI) of:	**Quantitative amount should be declared rounded to:**
< 25 mg or mcg (i.e., iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B6, vitamin B12, pantothenic acid, zinc, copper, and manganese)	The nearest tenth of a mg or mcg per serving OR The nearest hundredth or thousandth of a mg or mcg, if that level of specificity is necessary to attain a value that is at least 2% of the RDI in a serving of the food, unless this would not be accurate given the variation of the nutrient in the food supply
≥ 25 mg or mcg, but < 250 mg or mcg (i.e., vitamin C, vitamin K, biotin, iodine, selenium, chromium, and molybdenum)	The nearest 1 mg or mcg per serving
≥ 250 mg or mcg, but < 500 mg or mcg (i.e. folate and magnesium)	The nearest 5 mg or mcg per serving
≥ 500 mg or mcg (i.e. vitamin A, calcium, phosphorous, chloride, potassium, and choline)	The nearest 10 mg or mcg per serving

Public Comments

FDA is accepting public comments on all topics covered in the Q&A Draft Guidance, but is particularly interested in responses to the following questions:

- What, if any, concerns are there for manufacturers to use Brix values from 21 C.F.R. 101.30 when calculating the added sugars content of products containing fruit juice concentrates?
- For purposes of calculating the amount of added sugars, what, if any, concerns are there if FDA considers that all of the water in a formulation containing fruit or vegetable juice concentrate is used to reconstitute the fruit or vegetable juice?
- What, if any, concerns are there if FDA considers that all of the water that has been removed from a product during processing contributes towards the concentration of juice added as an ingredient during the formulation of the product?

Comments on the Q&A Draft Guidance should be submitted by March 6, 2017.

RACC Draft Guidance

The second draft guidance provides additional information about the tables of RACCs per eating occasion in FDA's regulations, which manufacturers must use to determine the serving size that is declared on the label. These tables provide three columns of information: (1) the name of the product categories; (2) the relevant RACCs as determined by FDA; and (3) appropriate label statements, which provide examples of serving size statements. The RACC Draft Guidance adds a fourth column, which contains a non-exhaustive list of examples of products that fall within each product category. This information is intended to help manufacturers identify the appropriate food category to which their product belongs.

For instance, the draft guidance provides the following list of examples of "yogurt": "All form of yogurts: drinkable, not-drinkable, plain flavored, and sweetened with or without fruit, nuts and other ingredients (e.g., granola) packaged together or in separate compartments that are mixed together for consumption." Although these examples appear to be relatively straightforward and noncontroversial, food manufacturers should review the draft guidance as needed to ensure that it accurately covers their products.

Comments on the RACC Draft Guidance should be submitted by March 6, 2017.

Covington & Burling LLP continues to monitor developments in food labeling requirements, and in particular, FDA's actions on dietary fiber, added sugars, and other actions related to FDA's revisions to nutrition information. If you have any questions concerning food labeling developments discussed in this alert or other food regulatory matters or would like assistance in preparing comments to FDA on the issues describe above, please contact any of the following attorneys in our Food & Drug Practice group or visit our food, beverage and dietary supplements practice website:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jeannie Perron	+1 202 662 5687	jperron@cov.com

Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com
Stephanie Resnik	+1 202 662 5945	sresnik@cov.com
Bianca Nunes	+1 202 662 5149	bnunes@cov.com