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Decoding New FDA Nutrition And Supplement Facts Guidance

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The U.S. Food and Drug Administration continues to fulfill its promise to provide food and dietary supplement companies with additional guidance on complying with the new final rules amending nutrition facts label regulations. In early January, the FDA issued a draft guidance entitled "Questions and Answers on the Nutrition and Supplement Facts Labels Related to The Compliance Date, Added Sugars, and Declaration of Quantitative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." The draft guidance is a compilation of questions and answers on a variety of topics aimed to assist food and dietary supplement firms to achieve compliance with the new labeling requirements.

While FDA guidance documents do not establish legally enforceable responsibilities, they do outline the agency's current thinking on a topic and can be helpful when determining how to best comply with new regulatory requirements. We summarize some of the key points below.

Compliance Date

In the draft guidance, the FDA clarified when products need to comply with the new labeling requirements. Specifically:

- Products that are labeled on or after July 26, 2018 (or July 26, 2019, for manufacturers with less than $10 million in annual food sales), must bear a nutrition label that meets the new labeling requirements.

- Products labeled before July 26, 2018 (or July 26, 2019, respectively), do not need to be in compliance with the new labeling requirements.[1]

How Will FDA Determine When a Product was Labeled?

The FDA noted that the agency will not consider the location of a food in the distribution chain to determine the compliance date for a particular product.[2] The agency will "consider the date the food product was labeled for purposes of determining the compliance date." Based on this interpretation, as long as the product is labeled *before* July 26, 2018, it does not need to be in compliance with the new

labeling requirements, regardless of where it is in the distribution chain (e.g., at the manufacturing facility waiting distribution, at a warehouse, in transit or on a store shelf).[3]

The FDA also noted that it does not object to the use of a "sticker" as a way to update a nutrition facts label before new packaging is printed. If a company decides to use a sticker, it "should not cover any other mandatory information and should adhere to the package during normal handling.[4]"

Annual Company Sales

The FDA also provides guidance on how to determine whether a company has $10 million or more in annual food sales in the draft guidance. To that end, a company can:

- Either take the smallest sales volume from the previous three years; or
- Take the average of the previous three years sales volume[5].

According to the FDA, a firm's total domestic and international food sales "best reflects" the firm's resources and its ability to comply with the new labeling requirements.[6]

Labeling of Added Sugars

With regard to the labeling of added sugars, the FDA provided some additional guidance with regards to fruits and vegetables that have been processed to change their form:

- 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, the agency will not consider the sugars contributed from the portion of the fruit or vegetable that is typically eaten, which is used to make that 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, the sugars in such an ingredient are consistent with how the agency considers the sugars in fruit juice concentrates.
- If sugars are in excess of what would be expected from an ingredient made from 100 percent fruits or vegetables, those sugars must be declared as added sugars.[7]

Sugars Present in Sweet Fermented Beverages

The FDA noted that if a fermented beverage contains "only" sugars that meet the definition of added sugars, "then the amount of sugars present in a serving of the product after fermentation must be declared as both total and added sugars.[8]" The FDA notes that if a fermented beverage contains both sugars that do and do not meet the definition of "added sugars," a firm can determine the amount of total sugars in the finished foods analytically.[9]

If the firm has no way to determine a "reasonable approximation" of the amount of added sugars in the finished product, "but you have reason to believe that a significant reduction of added sugars took place

during fermentation," the FDA offers the option of submitting a citizen petition per 21 CFR 10.30 to request an alternative means of compliance. The citizen petition should provide "scientific data or other information as to why the amount of added sugars in a serving of the product is likely to have a significant reduction in added sugars compared to the amount added prior to fermentation.[10]" The scientific data should also include the reason why the firm is unable to determine a reasonable approximation of the amount of added sugars in a serving of the finished product and a description of the process that the firm used to arrive at that conclusion.[11]

Declaration of Quantitative Amounts of Vitamins and Minerals

In the draft guidance, the FDA discusses the requirements for the declaration of quantitative amounts of vitamins and minerals declared on the nutrition and supplement facts labels. 21 CFR 101.9(c)(8)(iii) requires that:

> the quantitative amounts of vitamins and minerals, excluding sodium, be the amount of the vitamin or mineral included in a serving of the product using the units of measurement and the levels of significance given in 21 CFR 101.9(c)(8)(iv)(which refers to the Reference Daily Intakes (RDI) table).[12]

With regard to conventional foods, vitamins and minerals present at "less than 2 percent of the RDI" are not required to be declared on the nutrition facts label.[13] They may, however, be declared as "zero" or by the use of an asterisk that links the vitamin or mineral to the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)" or "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." If Vitamin D, calcium, iron or potassium is present in less than 2 percent of the RDI, a label declaration is not required if the statement "Not a significant source of ___(listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values.[14]

For dietary supplements, the amounts of vitamins and minerals with an RDI *must* be declared on the supplement facts labels when they are present in "quantitative amounts by weight that equal 2 percent or more of the RDI in accordance with 21 CFR 101.9(c).[15]" Any other vitamins and minerals listed in 21 CFR 101.9(c)(8)(iv) or (c)(9) may be declared, "but must be declared when added to the product for the purposes of supplementation, or when a claim is made about them.[16]" Vitamins and minerals may not be declared on the supplement facts label if they are present in amounts corresponding to less than 2 percent of the RDI for vitamins and minerals (21 CFR 101.36(b)(2)(i)).

The FDA recognized that the declaration requirements are different between conventional foods (i.e., quantitative amounts may be declared on the nutrition facts label when present in quantities of less than 2 percent of the RDI per serving whereas they must not be declared on the supplement facts labels when present in such small amounts), and recommended that firms use the "same principles" for declaration of vitamins and minerals on both the nutrition facts and supplement facts panels for consistency. To that end, the FDA is making the following recommendations[17]:

- The quantitative amount of vitamins and minerals with an RDI of less than 25 milligrams or micrograms (mcg) (i.e., iron, vitamin D, vitamin E, thiamin, riboflavin, niacin, vitamin B6, Vitamin B12, pantothenic acid, zinc, copper, and manganese) should be declared to the nearest tenth of a milligram or microgram per serving. However, the amounts may be declared to the nearest hundredth or thousandth of a milligram or microgram when that value is at least 2 percent of the RDI in a serving of food, and therefore, sufficient to declare the quantitative amount of the

nutrient on the supplement facts label.

- A quantitative amount of vitamins or minerals with an RDI of at least 25 mg or mcg, but less than 250 mg or mcg (i.e., vitamin C, vitamin K, biotin, iodine, selenium, chromium, and molybdenum), should be declared to the nearest milligram or microgram per showing.

- A quantitative amount of vitamins and minerals with an RDI of at least 250 mg or mcg, but less than 500 mg or mcg (i.e., folate and magnesium), should be rounded to the nearest 5 mg or mcg per serving.

- A quantitative amount of vitamins or minerals with an RDI of 500 mg or mcg or greater (i.e., Vitamin A, calcium, phosphorous, chloride, potassium, and choline) should be rounded to the nearest 10 mg or mcg per serving.

The FDA noted that manufacturers may calculate the percent DV for all nutrients other than protein by dividing either the amount of the nutrient declared on the label or the actual amount of the nutrient (before rounding) to provide for the greatest amount of consistency on the food label.[18] The agency also included a table with rounding recommendations for vitamins and minerals.

Comments on the draft guidance may be submitted here by March 6, 2017. While the FDA is inviting comments on any of the topics covered by the draft guidance, the agency is particularly interested in responses to the following questions:

1. What, if any, concerns are there for manufacturers to use Brix values from 21 CFR 101.30 when calculating the added sugars content of products containing fruit juice concentrates?

2. For purposes of calculating the amount of added sugars, what, if any, concerns are there if we consider that all of the water in a formulation with fruit or vegetable concentrate is used to reconstitute the fruit or vegetable juice?

3. What, if any, concerns are there if we consider 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?

The FDA also issued a companion draft guidance entitled “Reference Amounts Customarily Consumed: List of Products for Each Product Category.” This second draft guidance provides examples of products that belong in each of the product categories included in the tables of reference amounts customarily consumed (RACCs) per rating occasion established in 21 CFR 101.12(b).

A copy of the draft guidance can be found here. Any comments may be submitted by March 6, 2018.

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[1] See draft guidance Section III, Question #1.

[2] Id.

[3] Id.

[4] Id.

[5] See draft guidance, Section III, Question 2.

[6] Id.

[7] See draft guidance, Section III, Question 6.

[8] See draft guidance, Section III, Question 15.

[9] Id.

[10] Id.

[11] Id.

[12] See draft Guidance, Section III, Question 20.

[13] Id.

[14] Id.

[15] Id.

[16] Id.

[17] Id.

[18] Id.