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FDA Issues Supplemental Proposed Rule on Changes to Nutrition Labels

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Food & Drug

Today FDA published a supplemental notice of proposed rulemaking[1] to revise certain provisions of its proposed rule, issued in March 2014,[2] that would amend FDA's nutrition labeling requirements for conventional foods and dietary supplements. The supplemental proposed rule would require declaration of the percent daily value (% DV) for added sugars on the Nutrition Facts panel (NFP) and Supplement Facts panel (SFP) and shorten the current footnote on the NFP. FDA states that these proposed revisions were prompted by the information on added sugars presented in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* (the 2015 DGAC report)[3] and by the results of FDA's consumer research studies on format options for footnote text and added sugars declaration.

In addition, in response to comments on the March 2014 proposed rule and the results of FDA's consumer research studies, the agency has tentatively decided to withdraw its alternate design format for the NFP, which would have grouped nutrients into categories such as "avoid too much" and "get enough."

FDA invites public comments on certain issues discussed in the supplemental notice of proposed rulemaking by October 13, 2015.

Added Sugars Declaration

The supplemental proposed rule would require a declaration of added sugars underneath the sugars declaration in the NFP and SFP, establish a daily reference value (DRV) for added sugars, and require the % DV declaration of added sugars on the NFP and SFP. The DRV for added sugars would be 50 g for children 4 years of age and older, and 25 g for children ages 1-

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[1] *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Supplemental Proposed Rule To Solicit Comment on Limited Additional Provisions, 80 Fed. Reg. 44,303 (July 27, 2015), available here.

[2] *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11,880 (Mar. 3, 2014), available here. For additional information about the March 2014 proposed rule, see our previous client alert, FDA Publishes Proposed Rules on Changes to Nutrition Labels (Mar. 4, 2014), available here.

[3] The 2015 DGAC report is available here. For additional information about the 2015 DGAC report, see our previous client alert, Dietary Guidelines Advisory Committee Releases Report with Recommendations for the 2015 Dietary Guidelines for Americans (Feb. 23, 2015), available here.

3, based on the recommendation in the 2015 DGAC report that the daily intake of calories from added sugars should not exceed 10% of total calories.

Although the March 2014 proposed rule also would have required declaration of added sugars, it would not have established a DRV for added sugars or required declaration of a % DV for added sugars. In fact, at the time FDA issued the proposed rule, the agency tentatively concluded that there was no sound scientific basis for establishing a DRV for added sugars.

FDA states that since then, new information on added sugars from the 2015 DGAC report has led the agency to reconsider its initial conclusions. Specifically, FDA concludes that the 2015 DGAC report found that dietary patterns that are associated with decreased risk of cardiovascular disease are characterized, in part, by a reduced intake of added sugars. FDA also relies on the 2015 DGAC report's recommendation that individuals should limit added sugars to a maximum of 10% of total daily caloric intake. The DGAC's added sugars recommendation was based, in part, on the DGAC's food pattern modeling analysis, which determined that after meeting food group and nutrient recommendations, between 3 to 9% of calories are available to be consumed as added sugars.

While FDA adopted the DGAC's recommendation that the NFP and SFP identify the amount of added sugars in foods and beverages in both grams and as a % DV, the agency clarified that it independently reviewed the "scientific evidence underpinning" the DGAC's recommendations, as the 2015 DGAC report does not contain federal government recommendations and is currently under review by the federal government in updating the Dietary Guidelines for Americans. Based on its independent review, FDA concluded that the evidence provided a scientific basis for establishing a DRV for added sugars. However, as noted below, FDA specifically requests comment on the new information identified in the 2015 DGAC report regarding added sugars.

In addition, FDA acknowledged during its July 24, 2015, call for industry stakeholders that FDA's approach marks a departure from that taken by its Canadian counterpart, Health Canada, which recently decided not to require an added sugar declaration on Canadian food labels (although Health Canada has proposed including a % DV for total sugars based on a 100 g daily value for total sugars).

At this time, FDA is not proposing to establish a DRV for total sugars or to require declaration of total sugars as a percent of daily value, because, according to FDA, "there is no quantitative intake level or other reference amount for which there is sufficient scientific evidence upon which we can base a DRV for total sugars."

If FDA finalizes a mandatory declaration of added sugars, the agency intends to finalize a requirement that foods bear the term "Total Sugars" instead of "Sugars" on the label. This decision is based on the results of a consumer research study in which FDA tested various format options. Specifically, FDA found that the "Total Sugars + Added Sugars" format—i.e., indenting the added sugars declaration underneath the "Total Sugars" declaration—appeared to help study participants better understand that added sugars are part of the total amount of sugars.

Revised NFP Footnote

FDA also proposes to shorten the footnote in the NFP to read: "*The % Daily Value tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice." According to FDA, the proposed footnote explains the % DV in "the most concise manner by providing a brief description of '% Daily Value,' which is lacking in the current footnote." Under current FDA regulations, the footnote must list the reference values for certain nutrients for 2,000 and 2,500 calorie diets. Although the March 2014 proposed rule would have removed this requirement, it deferred establishing a revised footnote until after FDA conducted consumer research.

Under the supplemental proposed rule, the footnote requirement would not apply to the following types of foods:

- Foods that qualify for the simplified format and small or intermediate-sized packages, provided the labels of these products state "%DV = % Daily Value."
- Foods that can use the terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietary insignificant source of calories" on the label/labeling.

At this time, FDA is not proposing any revisions to the footnote text used in the SFP, but the agency is inviting comments on whether it should consider replacing the current SFP 2,000 calorie diet footnote with the part of the proposed NFP footnote that states "2,000 calories a day is used for general nutrition advice." This part of the proposed NFP footnote is the same as the succinct statement that will be required on menus and menu boards under FDA's final menu labeling rule.

Public Comment Period

FDA invites public comment on its proposed changes by October 13, 2015, but is limiting comments to the following issues:

1. new information from the 2015 DGAC report and the science upon which that report is based regarding added sugars;
2. the proposal to establish a DRV for added sugars and to require the declaration of the % DV for added sugars on the NFP and SFP;
3. using the term "Total Sugars" instead of "Sugars" on the label;
4. the proposed footnote text to be used on the NFP;
5. exemptions from the proposed footnote requirement;
6. whether FDA should make changes to the footnote used on the SFP;
7. whether there should be a footnote (and what it should say) on labels of food represented for infants 7-12 months of age or children 1-3 years of age; and
8. the consumer research studies FDA conducted and relied on in making its proposed revisions.

Covington is available to assist you further in understanding the potential impact of the proposed revisions and in drafting and submitting comments to FDA during the comment period.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug practice group:

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