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MEMORANDUM

From: Martin J. Hahn
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Re: **FDA Issues Supplemental Proposed Rule on Nutrition and Supplement Facts Labels**

Today the Food and Drug Administration (FDA) published a supplemental proposed rule, 1/ offering changes to the original March 2014 proposal to revise the format and content of the Nutrition and Supplement Facts Labels. 2/ The two key issues raised by the supplemental proposed rule are: (1) establishment of a Daily Reference Value (DRV) for added sugars, based on evidence presented in the 2015 Dietary Guidelines Advisory Committee (DGAC) Report; and (2) the proposed language for the footnote explaining the meaning of the percent Daily Value (DV), as well as which label formats are required to include this footnote. In support of the revised proposal, FDA also is making available for comment the results of two consumer studies conducted by the agency in 2014 and completed in June 2015. 3/

FDA will accept comments on the narrow set of issues raised by the supplemental proposal until October 13, 2015 and will accept comments on the consumer studies until September 25, 2015. FDA will not accept additional comments on other issues raised by the original proposal. In this memorandum, we provide a top-line summary of the proposed changes.

Proposed Changes Related to Added Sugars

FDA is proposing a number of revisions related to the proposed addition of added sugars to the Nutrition Facts Panel (NFP), including establishing a DRV for added sugars. Despite recognizing that the DGAC report "does not contain federal government recommendations" and that the "Federal government has not issued a final 2015 Dietary Guidelines for Americans report," FDA relies heavily on the report as justification for the proposed changes. The agency also cites its consumer research, which included questions regarding the declaration of added sugars. While the agency is evaluating whether it should require a declaration of added sugars in the NFP, the agency decision to propose a DRV for added sugars indicates the agency is very likely to include a declaration of added sugars when it finalizes the regulation. Below, we summarize the key proposed changes.

- Establishment of a DRV for Added Sugars: FDA is proposing to establish a DRV for added sugars of 50 grams (g) for adults and children 4 years and older, and of 25 g for children 1-3

1/ 79 Fed. Reg. 44303 (July 27, 2015).
2/ 78 Fed. Reg. 11879 (Mar. 3, 2014). See *HL Memorandum – FDA Proposes Revisions to Nutrition and Supplement Facts Labels and Serving Sizes*, February 27, 2014.
3/ 79 Fed. Reg. 44302 (July 27, 2015). The studies are to be posted to the docket on www.regulations.gov at Docket No. FDA-2012-N-1210.

years old. This proposal is based on FDA's "review of the science underlying the 2015 DGAC report," which, according to the agency, suggested an applicable reference amount for added sugars, i.e., limiting added sugars intake to no more than 10 percent of total daily caloric intake. This evidence caused FDA to reverse its tentative conclusion in the original proposed rule that "there was no sound scientific basis" to establish a DRV for added sugars. The agency is not proposing to establish a DRV for total sugars because it has found there is insufficient evidence to do so.

- Declaration of the Percent DV: FDA is proposing to require declaration of the percent DV for added sugars in the NFP. The agency explains that it received comments in response to the original proposal suggesting that if added sugars were required to be declared, adding a percent DV declaration would help consumers put the amount of added sugars in a serving of a product into the context of their daily diet. The proposal states that the consumer research the agency conducted did not test a version of the NFP that included the percent DV for added sugars, so FDA "do[es] not have data on how [that] information would affect consumer responses to an added sugars declaration."

- Format of Declaring Total Sugars and Added Sugars: FDA proposes to use the term "Total Sugars" instead of "Sugars" on the label. With this change, added sugars would appear indented below total sugars. This proposal is based on consumer research, showing that when "Total Sugars" was used as the heading, the majority of consumers correctly reported the amount of added sugars and accurately identified which product had less added sugars. In explaining the results of the study, FDA stated that a number of participants were confused about the distinction between sugars and added sugars, and that the declaration of higher amounts of added sugars "tended to produce more negative judgments about the product's healthfulness." The agency does not explain how it interprets these results to continue to justify requiring declaration of added sugars.

- Additional Rationale for Declaration of Added Sugars: The supplemental proposal discusses the evidence relied upon by the DGAC in its 2015 report, stating that FDA tentatively concludes that this evidence provides further support for the proposal to require the declaration of added sugars in the NFP and Supplement Facts panel. Specifically, FDA states, "the 2015 DGAC report provided evidence suggesting a strong association between a dietary pattern of intake characterized, in part, by a reduced intake of added sugars and a reduced risk of cardiovascular disease."

Proposed Changes Related to the Percent DV Footnote

- Footnote Language: In the supplemental proposal, FDA would require the following language to be used for the percent DV footnote:

  > "*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." 4/

  This language was selected based on FDA's review of the results of its consumer research, in which various footnote text options were tested. The proposed language is similar to the wording of one of the options tested in the study, except that the sentences have been reversed. FDA considered the reversal in the order important because it allows the language about the Daily Value to directly follow the asterisk in the "%DV" column. The agency acknowledges that the consumer research study "did not suggest strong support for a

4/ FDA notes that the second sentence is the same as the succinct statement that will be required on menu and menu boards under the menu labeling rule.

particular footnote," but adopts the language because "the language in this footnote was perceived by study participants to be more useful than the current footnote." Additionally, FDA cites research relied upon in the 1993 final rule showing that although most consumers do not notice footnotes, those who are given the information are able to interpret it appropriately. FDA explains it expects consumers who do read the statement will find it helpful in understanding the information in the NFP. Lastly, the agency notes that the proposed statement is shorter than the current statement to allow for more space on the label.

- Exceptions to Footnote Requirement: The proposal would exempt products that qualify for a simplified format, as well as small and intermediate packages, provided that the following abbreviated statement is used in the NFP: "%DV = % Daily Value." It also would add an exception for foods that qualify to 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" as defined in 21 CFR § 101.60(b). These products would be exempted because they have little to no impact on the average daily 2,000 calorie intake addressed by the footnote.

FDA also is requesting comment on whether it should make corresponding changes to the footnote used on the Supplement Facts label, and whether there should be a footnote on labels of food represented for infants 7 through 12 months of age or children 1 through 3 years of age, and, if so, what the footnote should say.

Publication of Consumer Studies

The two consumer research studies being added to the docket merit a careful review. While the studies have not yet been made available (as of publication of this memo), FDA provides the following description of the studies.

1. FDA, Eye-Tracking Experimental Study on Consumer Responses to Modifications to the Nutrition Facts Label Outlined in the Food and Drug Administration's Proposed Rulemaking, June 2015. This was a study in which 160 participants participated in a computer-based research of the potential effects of several possible changes to the label on consumer viewing and use of the label.

2. FDA, Experimental Study of Proposed Changes to the Nutrition Facts Label Formats, June 2015. This was a Web-based experiment, involving more than 5,000 participants, designed to explore whether modifications to the format of the Nutrition Facts label would affect consumers' interpretation of information on the Nutrition Facts label.

Importantly, in the *Federal Register* document regarding the publication of the two consumer studies for public comment, FDA explains that its review of comments submitted on the original proposal led the agency to tentatively reject further consideration of the so-called "Alternate" Nutrition Facts label format, which would have separated the panel into sections on "Quick Facts," "Avoid too much," and "Get enough." The agency states that the consumer research being made available does not change this planned approach.

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Should you have any questions, or wish to discuss these issues further, please contact us.