Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
T +1 202 637 5600
F +1 202 637 5910
www.hoganlovells.com

MEMORANDUM

From: Steven B. Steinborn
Samantha L. Dietle

Date: January 15, 2020

Re: **FDA Finalizes Nutrition Labeling Guidance Documents**

On December 31, 2019, the U.S. Food and Drug Administration (FDA) issued two final guidance documents to assist industry with compliance with the agency's updated Nutrition Facts labeling regulations. The first final guidance, entitled, "Guidance for Industry: 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" 1/ is a questions-and-answers style document and a helpful resource to consult for determining the serving size, number of servings, and appropriate Nutrition Facts Panel (NFP) format for different types of food packages. 2/ This guidance finalizes the draft guidance released in November 2018 with relatively few changes, as summarized below. 3/ FDA also updated one question in its final guidance document, "Nutrition and Supplement Facts Labels: Questions and Answers Related to the Compliance Date, Added Sugars, and Declaration of Quantitative Amounts of Vitamins and Minerals," 4/ with a new question-and-answer on the creation of sugars through the controlled hydrolysis of starch and other complex carbohydrates in the production of plant-based beverages, as discussed further below.

FDA's revisions in the final serving size guidance from the draft guidance are as follows:

- Non-juice beverages for infants and children. FDA amended its response regarding the appropriate reference amount customarily consumed (RACC) for non-juice beverages for infants and children. FDA acknowledges that there are more products available in the marketplace now for infants and children than when the nutrition labeling regulations were

1/ The final guidance is *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-serving-sizes-foods-can-reasonably-be-consumed-one-eating-occasion-reference.

2/ (1) "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain Reference Amounts Customarily Consumed; Serving Size for Breath Mints; and Technical Amendments," 81 F.R. 34000; and (2) "Food Labeling: Revision of the Nutrition and Supplement Facts Labels." 81 F.R. 33742.

3/ For our previous summary of the draft guidance, see our memo, FDA Issues Two Guidance Documents on New Nutrition Labeling Requirements, *available at* https://www.hlfoodlaw.com/wp-content/uploads/sites/357/2018/11/HL-Memo-FDA-Issues-Two-Guidance-Documents-on-New-Nutrition-Labeling-Re....pdf.

4/ The final guidance is *available at* https://www.fda.gov/media/117402/download.

originally promulgated, and that the agency intends to view available information and consider next steps with regard to this category of products.

- Simplified NFP format and "not a significant source" footnote. FDA expanded its question-and-answer regarding the use of the simplified NFP format and the "not a significant source of" footnote. Previously, this question was focused on sugar free gum; FDA has broadened the response to be applicable to any product in a small package that qualifies for the use of the simplified format. Under these circumstances, the label may state "not a significant source of other nutrients" in lieu of listing each nutrient separately.

- Placement of NFP on bottom of package. FDA revised its response regarding the placement of the NFP on the bottom of a package; FDA explains this is generally not compliant with FDA's regulations, unless the bottom of the package is visible during normal retail display and consumer handling, as with some frozen food packages or containers of gum or mints.

FDA also revised its added sugars Q&A guidance document to provide that sugars created through the hydrolysis of starch or other complex carbohydrates in the production of plant-based beverages (such as beverages made from oats and rice) must be declared as added sugars in the Nutrition Facts Panel. FDA explains that it considers sugars created through the hydrolysis of starch or other complex carbohydrates inherent to grains to be the same as sugars created through the hydrolysis of starch in the production of ingredients, such as maltodextrins, because in both cases the sugars are created through controlled hydrolysis. Because the hydrolysis is controlled, FDA maintains that manufacturers can determine the amount of sugars created and present in the final food.

* * *

We will continue to monitor FDA's implementation of the new food labeling requirements. Should you have any questions on this or any other matter, please do not hesitate to contact us.