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MEMORANDUM

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Date: March 5, 2018

Re: FDA Issues Guidance on Nutrition Labeling Regulations, Added Sugar Declarations for Honey, Maple Syrup, and Certain Cranberry Products, and Proper Labeling of Honey Products

On March 1, 2018, Food and Drug Administration (FDA or the agency) Commissioner Dr. Scott Gottlieb, M.D., announced new efforts to advance implementation of the new consumer Nutrition Facts label for foods, and with it a plethora of guidance documents on dietary fiber, Reference Amounts Customarily Consumed (RACCs) for product categories, declaration of added sugars on honey and similar products, and proper labeling of honey and honey products. 1/ We briefly discuss each of the following guidance documents further below:

- Final Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category
- 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; Small Entity Compliance Guide
- Final Guidance for Industry: Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-digestible Carbohydrates Submitted as a Citizen Petition (21 CFR 10.30)
- Draft Guidance for Industry: Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products
- Final Guidance for Industry: Proper Labeling of Honey and Honey Products

The deadline for submitting comments on the Draft Guidance concerning the declaration of added sugars for honey, maple syrup, and certain cranberry products is May 1, 2018. Comments should be submitted to Docket No. FDA-2018-D-0075. The other documents are Final Guidance, on which comments can be submitted at any time.

1/ FDA Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's new efforts to advance implementation of the new consumer Nutrition Facts label for foods (Mar. 1, 2018), available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm598808.htm.

Background on Nutrition Labeling Rules

In May 2016, FDA issued two final rules amending the nutrition labeling requirements for conventional foods and dietary supplements 2/ and updating the regulations on serving sizes. 3/ Among the most significant changes were the mandatory declaration of added sugars and the establishment of a reference amount for added sugars, the revised definition of dietary fiber, and the serving size and dual-column labeling revisions. 4/ The final rules became effective July 26, 2016, and have a compliance date of July 26, 2018, for manufacturers with $10 million or more in annual food sales, and July 26, 2019, for manufacturers with less than $10 million in annual food sales. On October 2, 2017, FDA published a proposed rule to extend the compliance dates to January 1, 2020, for manufacturers with $10 million or more in annual food sales and to January 1, 2021, for manufacturers with less than $10 million in annual food sales. FDA also announced that pending completion of the rulemaking with respect to the compliance dates, the agency will exercise enforcement discretion with respect to the compliance dates announced in the final rules. 5/

The recent actions summarized in this memorandum shed further light on FDA's interpretation of these new regulations in advance of the compliance dates. In the future, FDA also intends to respond to citizen petitions requesting that the agency include additional non-digestible carbohydrates in the regulatory definition of "dietary fiber," finalize the rule regarding the compliance dates for the Nutrition Facts label rules, and issue several additional technical guidance documents related to nutrition labeling.

Final Guidance on Reference Amounts Customarily Consumed

FDA has finalized its guidance, originally issued in draft form in January 2017, providing examples of products that belong in each of the product categories in the tables in the regulation on RACCs per Eating Occasion established in 21 CFR § 101.12(b). 6/ The Final Guidance is intended to help industry identify the product category to which specific products belong, but is not meant to provide an all-inclusive list of products that are available on the market for each product category.

In November 2016, FDA also published a Request for Information and Comments seeking public input on the appropriate RACC and product category for flavored nut butter spreads (*e.g.*, cocoa, cookie, and coffee flavored), and products that can be used to fill cupcakes and other desserts, such as cakes and pastries. FDA sought comment in part because it had received a citizen petition

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2/ Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742 (May 25, 2016).

3/ 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 Fed. Reg. 34,000 (May 27, 2016).

4/ *See* HL Memorandum - FDA Revises Nutrition and Supplement Facts Labels and Rules for Serving Sizes (May 25, 2016).

5/ Food Labeling: Revision of the Nutrition and Supplement Facts Labels and 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; Proposed Extension of Compliance Dates, 82 Fed Reg. 45,753 (Oct. 2, 2017).

6/ Reference Amounts Customarily Consumed: List of Products for Each Product Category: Guidance for Industry (Feb. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM535370.pdf.

requesting that FDA either issue guidance recognizing that "nut cocoa-based spreads" fall within the "Honey, jams, jellies, fruit butter, molasses'" category for purposes of RACC determination, or amend the regulation to establish a new RACC category for "nut cocoa-based spreads" with a RACC of 1 tablespoon.

Consistent with the Draft Guidance, FDA has determined that flavored nut butter spreads are comparable to nut butters and belong in the "Nut and seed butters, pastes, or creams" product category with a RACC of two tablespoons. In addition to clarifying the agency's position on this issue, the Final Guidance includes modest changes from the Draft Guidance made in response to comments received from the public.

Small Entity Compliance Guide on Revisions to the Serving Size Regulations

FDA has issued a Small Entity Compliance Guide (SECG) summarizing the final rule revising FDA's serving size regulations. 7/ The SECG provides a high-level summary of a variety of issues, including:

- Key definitions such as "serving size" and "single-serving container";
- Requirements for dual-column labeling;
- Product categories that are updated, modified, or established in the final rule;
- The scope of foods covered by the rule;
- Labeling for single-serving containers that contain more than 150% and less than 200% of the RACC;
- The effect of the rule on nutrient content claims and health claims;
- Determining the appropriate serving size for products, including an identification of products with special RACC rules; and
- The consequences of failure to comply with the rule.

The SECG also replicates the RACC tables from the final rule. Comments on the SECG can be submitted at any time to Docket No. FDA-2004-N-0258.

Final Guidance on Scientific Evaluation of Dietary Fiber

FDA has issued Final Guidance explaining the agency's views on the evidence needed to support a petition to add a substance to the list of recognized dietary fibers in FDA's newly enacted dietary fiber definition. 8/ By way of background, the May 2016 Nutrition and Supplemental Facts regulations established for the first time a definition for "dietary fiber," which became effective on July 26, 2016. The regulation defines "dietary fiber" to include, among other things, isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. The definition also includes seven isolated

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7/ 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—Small Entity Compliance Guide (Feb. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM594798.pdf.

8/ "Scientific Evaluation of the Evidence on the Beneficial Physiological Effects of Isolated or Synthetic Non-Digestible Carbohydrates Submitted as a Citizen Petition" (Feb. 2018), available at https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM528533.pdf. FDA also has updated its online Questions and Answers for Industry on Dietary Fiber, available at https://www.fda.gov/Food/LabelingNutrition/ucm528582.htm.

or synthetic non-digestible carbohydrates that FDA has recognized as having beneficial effects for human health when added to food.

Manufacturers may request that FDA amend the dietary fiber definition to recognize additional substances as dietary fiber through the citizen petition process in 21 C.F.R. § 10.30. If the substance is the subject of an authorized health claim, manufacturers also may use the health claim petition process in 21 C.F.R. § 101.70. If an isolated or synthetic non-digestible carbohydrate meets the definition of dietary fiber, FDA will add it to the list of dietary fibers in the definition under 21 C.F.R. § 101.9(c)(6)(i).

In November 2016, FDA issued Draft Guidance explaining the agency's thinking on information needed when submitting a citizen petition and the approach FDA plans to use for evaluating scientific evidence to determine whether an isolated or synthetic non-digestible carbohydrate that is added to food has a physiological effect that is beneficial to human health. 9/ The Final Guidance includes further clarification, as well as changes FDA made in response to comments received on the Draft Guidance.

For example, the Final Guidance clarifies that in order for a study to assess whether a non-digestible carbohydrate reduces blood glucose and/or insulin levels, it should be added to a food or beverage containing sugar or starch and should not replace any sugars or starches, because those refined carbohydrates cause the rise in blood glucose levels. FDA also said it is important that the non-digestible carbohydrate be added to a food or beverage with the same amount of sugar or refined carbohydrate as in the food or beverage that is provided to the study's control group.

The Final Guidance also takes a different position on the types of evidence FDA will consider as part of a science review. FDA states in the Final Guidance that it intends to consider evidence from studies with subjects who have a disease that is associated with the beneficial physiological effect of interest (e.g., lowering blood sugar and/or insulin) in considering whether the research supports a finding that an non-digestible carbohydrate may have a beneficial effect in "healthy" individuals who do not have the disease. The Final Guidance also provides additional detail and clarity on the physiological endpoints that FDA considers when reviewing scientific evidence and factors FDA considers when evaluating the strength of the scientific evidence.

In addition to clarifying its views on various aspects of the scientific review process, the Final Guidance also states that FDA plans to issue subsequent guidance documents addressing questions about "intrinsic and intact" fibers, the degree to which a non-digestible carbohydrate can be isolated or synthesized from its original plant source, but still be considered intrinsic and intact, and whether plant cell wall fibers containing a mix or combination of non-digestible carbohydrates would be an intrinsic and intact dietary fiber.

Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products

FDA issued a Draft Guidance to advise food manufacturers of FDA's intent to exercise enforcement discretion related to the use in the Nutrition Facts label of a symbol "†" immediately after the added sugars percent Daily Value information on single ingredient packages, on containers of pure honey or pure maple syrup, and on certain dried cranberry and cranberry juice products that are sweetened with added sugars, and that contain total sugars at levels no greater than comparable products with

9/ *See* HL Memorandum – FDA Issues Draft Guidance and Request for Information on Scientific Evaluation of Dietary Fiber (Dec. 16, 2016).

endogenous (inherent) sugars, but no added sugars. 10/ The "†" symbol would direct consumers to truthful and non-misleading statements on the package outside the Nutrition Facts label that would need to comply with applicable FDA statutory and regulatory requirements.

With respect to the labeling of single ingredient packages of pure honey or pure maple syrup, FDA explained this enforcement discretion is a response to concerns from stakeholders that consumers might misinterpret the added sugars declaration to mean that non-endogenous sweeteners, such as corn syrup or cane sugar, have been added to the pure product. Manufacturers could explain, through the use of such statements, that no sugar was added to the pure honey or pure maple syrup.

With respect to the labeling of certain cranberry products, FDA explained that cranberries are a naturally tart fruit, and certain dried cranberries and cranberry juice products have added sugars added to them to bring the total sugars per serving up to levels comparable to the levels of non-cranberry competitor products that contain equivalent amounts of total sugars, but whose labels list zero "added sugars" because their fruit products are inherently sweet. Stakeholders were concerned that consumers may think certain cranberry products are less nutritious than these competitor products because of the added sugars declaration. Manufacturers could explain, through the use of truthful and not misleading statements, that no sugar was added to the pure honey or pure maple syrup or that the added sugars added to dried cranberries or the cranberry juice product are meant to increase the palatability of the naturally tart fruit and that the amount of total sugars per serving is at a level that does not exceed the amount of total sugars in a comparable product with no added sugars.

FDA believes that permitting these factual statements to be referenced by the "†" symbol immediately following the added sugars percent Daily Value will address the concerns about these specific products.

Proper Labeling of Honey and Honey Products

Finally, FDA issued Final Guidance on the "Proper Labeling of Honey and Honey Products" that includes a series of questions and answers on honey labeling, focusing in particular on the labeling of products consisting of honey with added corn syrup or cane sugar, flavored honey, and blends of honey with other ingredients. 11/ There were minimal changes from FDA's Draft Guidance on the same issue. The Final Guidance states that honey with added cane sugar or corn syrup cannot be labeled as "honey," but rather must be identified as a blend. It also states that the source of honey is not required to be declared on labels, but the name of the plant or blossom may be identified if there is supporting information that the plant or blossom is the chief floral source of the honey. For example, names such as "Orange Blossom Honey," "Clover Honey," or "Wild Flower Honey" are acceptable. Additionally, the Final Guidance describes the labeling requirements for honeys that contain a flavor ingredient. Lastly, the Final Guidance provides several examples describing FDA's enforcement authorities for food products that are represented solely as "honey," but contain other ingredients.

10/ FDA Draft Guidance for Industry, The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products: Guidance for Industry (Feb. 2018) https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM596469.pdf.

11/ Final Guidance for Industry: Proper Labeling of Honey and Honey Products (Feb. 2018) https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM595961.pdf.

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We will continue to monitor developments concerning FDA's nutrition labeling regulations. Should you have any questions, or wish to discuss these issues further, please contact us.