COVINGTON

FDA Issues Guidance on Dietary Fiber and Added Sugars and Announces "Next Steps"

March 5, 2018

Food, Beverage, and Dietary Supplements

On March 1, FDA issued several guidance documents related to the nutrition facts label (NFL) final rule, including: the long-awaited final guidance on the scientific evaluation of petitions requesting approval of ingredients as dietary fiber; a draft guidance on how to declare added sugars on honey, maple syrup, and certain cranberry products; a final guidance on the proper labeling of honey and honey products; and two final guidance documents on reference amounts. This alert summarizes FDA's final fiber guidance and draft added sugars guidance and identifies some additional nutrition-related activities that FDA intends to commence "this spring."[1]

FDA's Final Guidance on How it will Evaluate Ingredients Seeking Approval as Dietary Fiber

How FDA will review the scientific evidence in dietary fiber petitions

FDA's final guidance[2] sets forth the standard FDA will use to evaluate isolated or synthetic nondigestible carbohydrates (NDCs) to determine whether they meet its definition of dietary fiber in order to be declared in the amount of dietary fiber on the NFL. The final guidance provides additional details and clarity on the type and quality of studies FDA will review in making its determination, beyond what was set forth in the agency's draft guidance.[3] The final

[1] FDA's two final reference amount guidances are: *Guidance for Industry: Reference Amounts Customarily Consumed: List of Products for Each Product Category* (Feb. 2018), available here; and *Guidance for Industry: 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 here. As these are rather straightforward, we have not addressed them here.

[2] *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)* (Feb. 2018).

[3] In November 2016, FDA issued its Scientific Review of 26 non-digestible carbohydrates (NDCs), as well as the draft guidance on its standards for evaluating the scientific information in citizen petitions seeking approval of potential dietary fibers. For a discussion of the draft

guidance retains FDA's position that the agency will look primarily to robust human clinical intervention studies (e.g., randomized, double-blinded, placebo controlled) in assessing whether an ingredient sufficiently demonstrates a beneficial physiological effect in humans.

The final guidance also identifies the same five clinical benefits FDA listed in the draft guidance as examples of beneficial physiological effects associated with the consumption of NDCs -- lowering blood glucose and cholesterol levels, lowering blood pressure, increase in frequency of bowel movements, increased mineral absorption in the intestinal tract, and reduced energy intake. A NDC must have at least one beneficial physiological effect that is demonstrated in robust human clinical intervention studies in order to meet FDA's definition of dietary fiber. For each of these identified beneficial physiological effects, the final guidance provides additional clarity on what FDA would expect to see in a study, including the types of clinical endpoints to use, the length of time the study should last, and other study details.[4]

One change in the final guidance is that FDA will accept and review well-controlled intervention studies using subjects with a disease linked to the studied beneficial effect (e.g., cholesterol lowering), but only "when extrapolating to individuals who do not have the disease is scientifically appropriate."

In its constituent update and Commissioner Gottlieb's statement announcing the final guidance, FDA states that it is allowing companies with ingredients currently being reviewed by FDA to submit additional information, if necessary, to meet the standards FDA provided in the final guidance. FDA expects to issue responses this spring to the pending fiber approval requests.

Open questions for stakeholders to keep in mind

The final guidance leaves open several questions that FDA has yet to fully address.

- The final guidance removes previous statements about "intrinsic and intact" fibers. FDA states it will issue a subsequent guidance that addresses "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.
- The Q&A webpage released as part of FDA's constituent update states that FDA will use the rulemaking process to amend the definition of "dietary fiber," as required by regulation, but this should not foreclose FDA from considering using other mechanisms to more quickly notify stakeholders of approved fibers or to allow FDA to exercise enforcement discretion during the rulemaking process.

---

guidance, *see* FDA Issues Dietary Fiber Guidance and Scientific Review of 26 Fibers, Covington Client Alert (Nov. 30, 2016), available here.

[4] For example, FDA clarifies that in order for a study to assess whether an NDC reduces blood glucose and/or insulin levels, the NDC should be added to a food or beverage containing sugar or starch and should not replace any sugars or starches since those refined carbohydrates cause the rise in blood glucose levels. In addition, the NDC should be added to a food or beverage with the same amount of sugar or refined carbohydrate as the food or beverage that is provided to the study's control group.

- The Q&A webpage suggests that if a fiber petition remains pending as of the compliance date for the new NFL, manufacturers using that ingredient "cannot include those isolated or synthetic [NDCs] that are the subject of pending petitions in the declaration of 'dietary fiber.'" FDA has stated that it fully intends to extend the compliance date, and initiated the process to do so last fall through a proposed rule.

Draft Guidance on Declaring Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products

FDA also issued a draft guidance that provides alternative "added sugars" declarations on 100% honey, 100% maple syrup, and dried cranberries and cranberry juice products (where sugar has been added for palatability at levels comparable per serving to similar non-cranberry products, but whose labels list "0 added sugars" due to such products' inherent sweetness).[5] For 100% honey and 100% maple syrup products covered by the draft guidance, FDA intends to exercise enforcement discretion on labels that use a "†" symbol immediately following the added sugars percent Daily Value in the NFL that is linked elsewhere on the label to a truthful and non-misleading statement such as "† All these sugars are naturally occurring in honey." The same symbol is permitted in the NFL of dried cranberries and cranberry juice products (covered by the draft guidance) if the symbol is linked to a statement elsewhere on the label such as, "† Sugars added to improve the palatability of naturally tart cranberries. The 2015-2020 Dietary Guidelines for Americans state that that there is room for limited amounts of Added Sugars in the diet, especially from nutrient dense food like naturally tart cranberries." FDA requested that comments be submitted by May 1, 2018.

FDA also released a final guidance on how to properly label honey and honey products to help ensure that such products are not adulterated or misbranded.[6] The guidance provides that food that contains only honey must be named "honey," but that products consisting of honey and a sweetener cannot be labeled with the name "honey" because this name does not properly identify the basic nature of the food. Foods that do not follow these conventions would be considered adulterated and/or misbranded.

[5] *Draft Guidance: The Declaration of Added Sugars on Honey, Maple Syrup, and Certain Cranberry Products* (Feb. 2018). FDA provided the alternatives in response to concerns that consumers might misinterpret the added sugars declaration on "100%" honey and maple syrup products to mean that non-endogenous sweeteners (e.g., corn syrup or cane sugar) have been added to the pure product and to identify that the sugar added to naturally tart cranberries is no more than naturally-occurring sugar in similar products that do not declare added sugars.

[6] *Guidance for: Proper Labeling of Honey and Honey Products* (Feb. 2018).

Expect more from FDA this spring and beyond

Commissioner Gottlieb made several additional announcements, referencing the mid-January launch of his "Nutrition Action Plan,"[7] stating that in the coming weeks FDA intends to:

- issue guidance on "intrinsic and intact" fibers;
- issue final conclusions on the NDCs currently under FDA review;
- issue a final rule extending the compliance dates for the new version of the NFL;
- provide more details on a nutrition strategy to "reduce preventable death and disease through better nutrition."

In addition, Commissioner Gottlieb announced FDA's intent to "launch a major educational campaign for consumers surrounding the new [nutrition facts] label," including an educational campaign to help Americans use the new version of the new label and interpret the overall nutritional content of products.

Covington & Burling LLP continues to monitor developments in food labeling requirements, and in particular, FDA's actions on dietary fiber, added sugars, and other actions related to FDA's revisions to nutrition information. If you have any questions concerning food labeling developments discussed in this alert or other food regulatory matters or would like assistance in preparing comments to FDA on the issues describe above, please contact any of the following attorneys in our Food & Drug Practice group or visit our food, beverage and dietary supplements practice website:

Miriam Guggenheim	+1 202 662 5235	mguggenheim@cov.com
Jessica O'Connell	+1 202 662 5180	jpoconnell@cov.com
MaryJoy Ballantyne	+1 202 662 5933	mballantyne@cov.com
Stephanie Resnik	+1 202 662 5945	sresnik@cov.com
Bianca Nunes	+1 202 662 5149	bnunes@cov.com

[7] For a discussion of the Nutrition Action Plan, which is one of FDA's top four priorities for 2018, *see* FDA Announces "Nutrition Action Plan" while Stakeholders await Final Guidance on Nutrition Labeling, Covington Client Alert (Jan. 16, 2018), available here.