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FDA Issues Final Rules on Changes to Nutrition Labels

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Food & Drug

On Friday, May 20, 2016, FDA issued two final rules to revise the nutrition labeling requirements for conventional foods and dietary supplements—the first major revisions to the nutrition labels since they were originally required over 20 years ago.[1] Recognizing a shift in the average American's consumption habits and understanding of the Nutrition Facts label, the two rules include changes to the content and format of the Nutrition Facts label, as well as to the reference amounts that determine the serving sizes of conventional foods. FDA also finalized conforming changes to the Supplement Facts label.

The final rules largely incorporate the proposals FDA set forth in its two proposed rules, issued in March 2014,[2] as modified by its supplemental proposed rule, issued in July 2015.[3] We summarize below key provisions of the final rules that may be of interest to industry stakeholders, including those relating to added sugars, dietary fiber, and vitamin and mineral declarations, and highlight key differences between the proposed and final rules.

Revision of the Nutrition and Supplement Facts Labels

The final rule will implement a number of significant changes to the Nutrition and Supplement Facts labels. Highlights of these changes include the following:

Added Sugars. FDA will now require the use of the term "total sugars" instead of "sugars" in the total sugars declaration on the Nutrition and Supplement Facts labels, require the declaration of the gram amount of "added sugars" on an indented line underneath the "total sugars" declaration, establish a Daily Reference Value (DRV) for added sugars, and require the percent

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[1] *See* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, available here. *See* 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, available here.

[2] The March 2014 proposed rules are available here and here. For additional information about the March 2014 proposed rules, see our previous client alert, FDA Publishes Proposed Rules on Changes to Nutrition Labels (Mar. 4, 2014), available here.

[3] The July 2015 supplemental proposed rule is available here. For additional information about the July 2015 supplemental proposed rule, see our previous client alert, FDA Issues Supplemental Proposed Rule on Changes to Nutrition Labels (July 27, 2015), available here.

Daily Value (DV) declaration for added sugars on the Nutrition and Supplement Facts labels. As in the supplemental proposed rule, the DRV for added sugars is no more than 10% of total calories (i.e., 50 g for those 4 years of age and older, and 25 g for children ages 1-3). FDA based this DRV on the recommendation in the *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* and the 2015 *Dietary Guidelines for Americans* that the daily intake of calories from added sugars should not exceed 10% of total calories.[4] FDA likewise carried forward its proposal not to establish a DRV for total sugars or to require declaration of total sugars as a percent of daily value.

In the final rule, FDA acknowledged that its consumer research showed a statistically significant decrease in participants' understanding of total sugars in a serving of a product when a label included an added sugars declaration compared to when the label did not include such declaration. In order to reduce this confusion, the final rule requires the word "total" to describe the total amount of sugar in a product, adds the word "includes" in front of the added sugars declaration (i.e., "Includes X g Added Sugars") and minimizes the hairline between total sugars and added sugars.

The final rule defines the term "added sugars" as "sugars [that] are either added during the processing of foods, or are packaged as such," including:

- sugars (free, mono- and disaccharides);
- sugars from syrups and honey; and
- sugars from concentrated fruit or vegetable juices that are in excess of what would be expected from the same volume of 100% fruit or vegetable juice of the same type.

The term "added sugars" does not include:

- fruit or vegetable juice concentrated from 100% juices sold to consumers;
- fruit or vegetable juice concentrates used towards the total juice percentage label declaration under 21 C.F.R. 101.30 or for Brix standardization under 21 C.F.R. 102.33(g)(2);
- fruit juice concentrates which are used to formulate the fruit component of jellies, jams, or preserves in accordance with the standard of identities set forth in 21 C.F.R. 150.140 and 150.160; or
- or the fruit component of fruit spreads.

In determining which sugars to include in this definition, FDA considered the presence of added sugars as a component of dietary intake and whether it is consistent with the concept of "empty calories." This definition differs from FDA's proposal in that the final rule provides more detail on what would and would not be considered added sugar, and removes portions of the definition that would have inadvertently captured ingredients that FDA does not consider to be added

[4] The *Scientific Report of the 2015 Dietary Guidelines Advisory Committee* is available here. For additional information about this 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.

sugars, such as dairy ingredients. FDA likewise revised this definition to make it consistent with the requirements for use of the "no added sugars" nutrient content claim.

As in FDA's proposal, the final rule allows added sugars content to be expressed as zero if one serving of the food contains less than 0.5 grams of added sugars. A declaration of added sugars content is not required for foods that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol content.

The final rule also carries forward the proposed rule's added sugars recordkeeping requirements. Specifically, when a food contains both added and naturally-occurring sugars, the manufacturer must make and keep records to verify the declared amount of added sugars. The manufacturer also must make and keep such records for foods containing added sugars where the added sugars are subject to fermentation and/or non-enzymatic browning. In particular, these records should include all relevant scientific data and information relied upon by the manufacturer that demonstrates the amount of added sugars in the food after non-enzymatic browning and/or fermentation, as well as a narrative explaining why the data and information are sufficient to demonstrate the amount of added sugars declared in the finished food. Alternatively, manufacturers of such foods may make and keep records of the amount of added sugars added to the food before and during the processing of the food (and, if packaged as a separate ingredient, as packaged). Recognizing that there may be a small number of foods for which manufacturers have reason to believe that the amount of added sugars in the finished product is significantly less than the amount added prior to non-enzymatic browning and/or fermentation, FDA revised the final rule to permit manufacturers to submit a petition, under 21 C.F.R. 10.30, to request an alternative means of compliance. In response to comments raising concerns about these recordkeeping requirements exposing confidential commercial information or trade secrets to FDA, the agency stated that it would protect such information from disclosure, consistent with its statutory and regulation obligations, and recommended that manufacturers mark proprietary information as such before providing records to FDA.

FDA received a large number of comments on this controversial added sugars proposal. Highlights of the agency's responses to these comments include the following:

- FDA received comments suggesting that an added sugars declaration would be false and misleading because it would convey to the reasonable consumer that added sugars are chemically different than naturally-occurring sugars. FDA disagreed that a separate declaration necessarily implies a chemical or physiological distinction. In addition, FDA stated that a physiological or chemical distinction between added and naturally-occurring sugars is not a prerequisite to a mandatory nutrient declaration, because FDA did not rely on a causal relationship between consumption of added sugars *per se* and risk of a chronic disease. Rather, the agency considered the need for consumers to construct a healthy dietary pattern that is limited in added sugars to reduce the risk of cardiovascular disease and to meet nutrient needs within calorie limits. Accordingly, FDA concluded that it was appropriate to mandate the added sugars declaration to assist consumers in maintaining healthy dietary practices.
- In response to comments stating that the Institute of Medicine (IOM) is the appropriate body to establish a Dietary Reference Intake (DRI) upon which to base a DRV for added sugars, FDA acknowledged that a DRV that is derived primarily based on food pattern modeling is different from an upper limit (UL) that is determined by IOM. The agency nonetheless maintained that a food modeling-based DRV is a valid approach that

provides consumers with a tool they can use to help them put the amount of added sugars into the context of their total daily diet. FDA implied that food modeling would not be the most appropriate approach, however, if there were a direct relationship between added sugars consumption and disease risk.

- FDA declined requests to exempt certain nutrient-dense foods containing added sugars from the added sugars declaration requirement, reasoning that such an exemption might mislead consumers to believe these foods contain no added sugars. Acknowledging that some consumers may focus on the amount of added sugars in a product and judge it to be a less nutritious product despite its beneficial nutrients, FDA indicated that it plans to address this issue through consumer education. FDA similarly declined requests to exempt certain foods that contain added sugars for palatability (e.g., cranberry juice) from the added sugars declaration requirement, concluding that this information is necessary on all products so that consumers can make informed dietary choices. FDA indicated that food producers could, if they choose, convey the purpose of added sugars in a truthful and nonmisleading statement elsewhere on the food label.
- For a number of reasons, FDA likewise declined requests to declare the amounts of total sugars and added sugars in a household measurement (e.g., teaspoons), including because it would be difficult for the manufacturer to determine the volume contribution of added sugars and because of the limited space available on the label.

Dietary Fiber. The final rule incorporates two major changes to the dietary fiber declaration that were introduced in the proposed rule—a definition of "dietary fiber," a term that FDA had not previously defined, and an increase in the DRV from 25 grams to 28 grams.

- **Definition.** The final definition of dietary fiber is: "non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), and lignin that are intrinsic and intact in plants; 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."[5] Significantly shorter than the proposed definition, the final definition distinguishes between "isolated *or* synthetic" non-digestible carbohydrates and does not expressly refer to the citizen petition process as the means for obtaining FDA approval of "isolated or synthetic" substances as dietary fiber.

  FDA explains in the preamble that "intrinsic and intact" dietary fibers (FDA requires these dietary fibers to demonstrate both qualities) include brans obtained by grinding and "non-digestible carbohydrates that are created during normal food processing (e.g., cooking, rolling, or milling)" such as "non-digestible (resistant) starch in flaked corn cereal." In addition, FDA suggests that it would treat waxes, cutins, and suberin as it does lignin—as minor components included in calculating the amount of "intact and intrinsic" fibers

[5] 21 C.F.R. 101.9(c)(6)(i). FDA considers "intact" as having no relevant component removed or destroyed, "intrinsic" as originating and included wholly within a food, and that "intact and intrinsic fibers are naturally present such that they are integrated within the plant matrix and contain other nutrients naturally present in proportions that exist in the plant cell." Response to Comment 265. FDA uses "isolated" to describe "non-digestible carbohydrates that are isolated from plant sources such that they are no longer intrinsic or intact" and "synthetic" to describe "synthetic non-digestible carbohydrates that are not isolated from plant sources but rather chemically synthesized." *Id.*

declared as dietary fiber—because the new quantitative methods, such as AOAC 2011.25, include waxes, cutin, and suberin in the measurement of non-digestible carbohydrates.

- **FDA's final list of approved "isolated or synthetic" dietary fibers.** The final rule lists a handful of "isolated or synthetic" non-digestible carbohydrates that FDA has determined fit within its definition of dietary fiber because the substances benefit human health, including: [beta]-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose. FDA states that this list "is not exhaustive" and that as the science evolves (including endpoints establishing beneficial physiological effects) its list of "isolated or synthetic" dietary fibers may change.

  Notably absent from FDA's list of "isolated or synthetic" dietary fibers are ingredients such as inulin and other plant fibers. FDA states that it intends to publish "a separate notice to seek comment on the available scientific data on [isolated or synthetic] non-digestible carbohydrates to determine if we should consider additional non-digestible carbohydrates to be added to the list of dietary fiber." In this separate notice, FDA intends to "identify and summarize" "publically available clinical trial data . . . for non-digestible carbohydrates including inulin, bamboo fiber, soy fiber, pea fiber, wheat fiber, cotton seed fiber, sugar cane fiber, sugar beet fiber, and oat fiber." Companies who would like these carbohydrates to be included in FDA's list of approved dietary fibers could assist FDA by gathering and submitting to FDA credible human clinical data demonstrating the beneficial physiological effects of these substances.

- **Procedure to obtain FDA approval of "isolated or synthetic" dietary fibers.** The citizen petition process in 21 C.F.R. 10.30 will be the means for obtaining FDA approval of "isolated or synthetic" non-digestible carbohydrates as dietary fibers, although FDA concluded that it did not need to cite to this process specifically in the rule.

  In the preamble, FDA states that it intends to issue a guidance document that sets out the information and type of scientific evidence it will require in a citizen petition and the approach it intends to use to evaluate the submitted studies, including its approach for evaluating the strength of the scientific evidence. FDA clarifies that animal and in vitro studies will not be sufficient and that it will review FDAMA health claims on a "case-by-case basis." FDA identifies the types of physiological effects the agency considers to be beneficial to human health, including attenuation of blood glucose, attenuation of cholesterol levels (total or LDL), lowering of blood pressure, increased satiety, improved laxation/bowel function, and increased absorption of minerals. FDA distinguishes these effects from "processes" such as fermentation or changes in the microbiota in the large intestine, which FDA does not consider to be beneficial physiological effects.

- **Mandatory declaration and record keeping/access requirement.** Because the final rule retains dietary fiber as a mandatory declaration in 21 C.F.R. 101.9(c)(6)(i) (pursuant to FDCA 403(q)(1)(D)), an ingredient that falls within FDA's definition of dietary fiber—including substances on FDA's list of "isolated or synthetic" dietary fibers—must be included in the calculation of the amount of dietary fiber and declared on the Nutrition Facts label. Thus, if a food is comprised of dietary fiber that meets FDA's dietary fiber definition and non-digestible carbohydrates that do not, the final rule requires a manufacturer to make and keep (and make available for FDA inspection) written records for that food that substantiate the declaration of dietary fiber and the appropriate

designation of the other non-digestible carbohydrates as part of the Total Carbohydrate declaration.

- **Voluntary declarations of soluble and insoluble dietary fibers.** Despite comments opposing these terms, the final rule retains the terms "soluble" and "insoluble" and keeps these declarations voluntary. The final rule requires these fibers to meet FDA's definition of dietary fiber.
- **Caloric value**. The final rule includes the proposed caloric value of 2 calories per gram for soluble non-digestible carbohydrates, and does not modify the existing requirement to exclude insoluble non-digestible carbohydrates from the caloric calculation.
- **Compliance.** The final rule omits the specific AOAC testing methods that were included in the proposed rules. Compliance with the dietary fiber declaration, therefore, is determined by the general compliance requirements of 21 C.F.R. 101.9(g)(2), by using "appropriate methods as given in the 'Official Methods of Analysis of the AOAC International,', or if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures." After a lengthy discussion in the preamble on the various AOAC methods and non-AOAC methods available for calculating the amount of non-digestible carbohydrates, FDA explains that "'an equivalent AOAC method' means a reliable and appropriate method which can be used for measuring dietary fiber, soluble fiber, and insoluble fiber . . . with 3 or more monomeric units." FDA cautions, however, that even though a manufacturer may use an "equivalent AOAC method" to determine compliance, FDA will use "AOAC methods, including AOAC 2009.01 and AOAC 2011.25" because it considers these to be "reliable and appropriate methods to measure the amount of dietary fiber."

Vitamins and minerals of public health significance. The final rule incorporates FDA's proposal to update the vitamins and minerals "of public health significance," based on the agency's analysis of nutrient inadequacy. Under the final rule, manufacturers will need to declare the absolute amount (e.g., mg) and % DV of vitamin D, calcium, iron, and potassium. Declaration of vitamins A and C will become voluntary.

Revised Daily Values (DVs). FDA finalized its proposal to revise the DVs for certain nutrients, including calcium, sodium, dietary fiber, and vitamin D.

***Trans* Fat and "Other Carbohydrates."** FDA made no changes to the mandatory *trans* fat declaration, rejecting numerous requests to remove the mandatory *trans* fat declaration or to lower the amount that can be declared as zero (currently, below 0.5 grams per serving). The final rule no longer includes the voluntary declaration for "other carbohydrates."

Records Requirements. FDA finalized its proposed recordkeeping and records access requirements for nutrients for which "there is no suitable analytical procedure available to measure the quantity" including: (1) added sugars (when a food contains both naturally-occurring and added sugars and for sugar reduction calculations); (2) dietary fiber, including declared soluble and insoluble fibers (when a food contains non-digestible carbohydrates that do and do not meet FDA's dietary fiber definition); (3) vitamin E (when a food contains both RRR-alpha-tocopherol and all rac-alpha-tocopherol acetate); and (4) folate (when a food contains both folate and folic acid).

Format of the Nutrition Facts label and related changes. In addition to the changes noted above, the final rule will implement the following format changes to the Nutrition Facts label (but retain its current overall size):

- *Calories and Serving Size information*: (1) the "Calories from fat" declaration will be removed; (2) the "Calories" and "Servings per container" declarations will appear in an increased font size and bold type; and (3) the declaration of "Servings per container" will appear above the declaration of the serving size.
- *Footnote*: The final rule removes the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets, and replaces the current footnote with the following: "The % Daily Value (DV) 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."

The final rule does not, however, carry forward FDA's proposal to shift the % DV column to the left side of the label.

Serving Sizes

The second final rule complements FDA's changes to requirements for the Nutrition Facts label and, as proposed, implements a labeling scheme that distinguishes between foods that are likely to be consumed entirely in one sitting from foods that may be consumed over the course of multiple sittings or shared with other consumers. Central to the changes is FDA's interpretation that, by law, serving sizes must be based on amounts of foods and beverages that people are actually eating, not what they should be eating. According to the agency, the amounts of certain categories of food consumed by the American public have changed since 1993, when the previous reference amounts customarily consumed (RACCs) were published. For example, the reference amount used to set a serving of ice cream was previously 1/2 cup, but under the new RACCs is changing to 2/3 cup. Likewise, the reference amount for a serving of soda is increasing from 8 ounces to 12 ounces. Because the agency believes package size affects what people eat, FDA has concluded that increasing the RACCs and requiring dual-column labels for certain foods will enable consumers to easily understand the calories and nutrients they will get by consuming an entire container at once.

Highlights from the final rule include:

- **Single-serving containers and dual-column labeling.** The final rule requires products containing less than 200% of the RACC to be labeled as single-serving containers. For example, labels on 20 ounce bottles of soda must now declare calories and other nutrients for the entire package, rather than per serving, because people typically consume the entire bottle in one sitting. In contrast, containers of food with at least 200% and up to 300% of the RACC must include a dual-column label, with one column displaying the nutrition information for the entire container, and the second column displaying the preexisting requirement of nutrition information for the RACC-based serving size. The agency explains the dual-column requirement as allowing consumers to easily understand the amount of calories and nutrients involved in consuming the entire package or unit at once.

The upper limit of up to 300% is a notable change from the proposed rule, which would have required containers of foods up to 400% of the RACC to contain a dual-column label. As explained in the preamble to the final rule, FDA lowered the upper limit to 300% in response to many comments suggesting that more than 90% of food products have consumption levels that are 300% or less of the RACC at the 90th percentile. FDA agreed, noting that providing an upper limit at 300% of the RACC would ensure that dual-column labeling captures 90% of the consumption habits for about 91% of food products and limit the possibility that dual-column labeling will be required for package sizes that are not likely to be consumed in a single eating occasion. As the agency acknowledges in the preamble, lowering the upper limit of the requirement to up to 300% reduces the number of products for which dual-column labeling will be required.

- **Updated RACCs.** In the preamble to the final rule, FDA reiterates that it is required by statute to establish RACCs based upon actual consumption habits, and not on recommended serving sizes. FDA concluded from consumption data generated in the National Health and Nutrition Examination Surveys (NHANES) that some RACCs needed to be updated to reflect actual consumption patterns. The final rule amends RACCs for those categories of food for which NHANES data show median consumption has increased or decreased by at least 25% compared to the 1993 RACCs. As a result, FDA established new RACCs for several categories of food intended for adults, including:
  - Bagels, toaster pastries, muffins (excluding English muffins)
  - Carbonated and noncarbonated beverages, wine coolers, water
  - Coffee or tea flavored and sweetened
  - Fish, shellfish, or game meat, canned
  - Fruits used primarily as ingredients, avocado
  - Fruits used primarily as ingredients, others (cranberries, lemon, lime)
  - All other candies
  - Syrups

  In addition, FDA updated the RACCs for mediumweight and heavyweight breakfast cereals, although such changes did not appear in the proposed rule. Notably, FDA established a new RACC of 12 fluid ounces for soda, whereas the RACC for juices remains at 8 fluid ounces. The agency also updated the RACC for sugar, raising it from 5 g to 8 g.
- **Implications for nutrient content and health claims.** The updated RACCs have important implications for some nutrient content and health claims. As FDA acknowledged in the proposed rule and again acknowledges in the preamble to the final rule, some individual foods currently meeting the requirements for certain claims based on existing RACCs may become ineligible to bear such claims under updated RACCs. For example, a food that currently bears a “low fat” nutrient content claim may no longer qualify for that claim if its RACC is increased such that it now contains more than 3g fat per RACC.

  In the preamble to the final rule, FDA agrees with the comments suggesting the agency evaluate claim regulations and any change to eligibility for claims. However, FDA notes that changing nutrition labeling is a step-wise process, and that it intends to consider in a

future rulemaking issues such as whether any changes in eligibility for claims would assist consumers in constructing healthy diets and whether the criteria for claims remain appropriate. FDA further notes that the compliance period will allow manufacturers time to make necessary changes, such as discontinuing use of certain voluntary claims that, under the new RACCs, the products may no longer be eligible to make.

Consumer Outreach and Education

FDA intends to conduct consumer education and outreach on the Nutrition Facts label, including increasing the understanding of added sugars and other new components on the label, considerations for how to interpret the information on added sugars in the context of a healthy diet, and how all the information provided on the Nutrition Facts label is important to consider when constructing a healthy dietary pattern.

Compliance Date

Although the final rule becomes effective on July 26, 2016, manufacturers with $10 million or more in annual food sales will have until July 26, 2018, to comply with the rule; manufacturers with less than $10 million in annual food sales will have an additional year to comply, until July 26, 2019. During its May 20, 2016, call for industry stakeholders, FDA declined to respond to questions regarding whether all products that are on store shelves as of the respective compliance date must comply with the new labeling requirements, or whether FDA would measure compliance as of the product's manufacture date. The agency instead encouraged industry stakeholders to submit this question to FDA for further consideration. Given the limited number of packaging manufacturers, food companies should plan for making changes to their labels far in advance of their respective compliance dates.

Covington is experienced in advising clients on matters related to the labeling of conventional foods and dietary supplements and is available to provide individualized compliance counseling concerning these issues. 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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