COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Food & Drug

March 4, 2014

FDA PUBLISHES PROPOSED RULES ON CHANGES TO NUTRITION LABELS

On Monday, March 3, 2014, FDA published in the Federal Register two proposed rules that would revise the nutrition labeling of packaged foods and dietary supplements: "Food Labeling: Revision of the Nutrition and Supplement Facts Labels"[1] and "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."[2] Although published separately, the two proposed rules are closely related, and each informs the other. They include changes to how – and what – information is displayed in the Nutrition Facts label, as well as to the reference amounts for how the serving size of conventional foods will be determined. Conforming changes to the Supplement Facts panel are also proposed. FDA has made clear that front-of-pack labeling is outside of the scope of this proposed rulemaking, though the agency continues to consider this issue and may address it separately.

FDA states that these changes reflect the agency's recognition of a shift in the average American's consumption habits and understanding of the Nutrition Facts panel. The proposals are prompted, at least in part, by current scientific evidence, the dietary recommendations of the most recent consensus reports, citizen petitions and public comments received in response to FDA's advance notices of proposed rulemaking. The agency was particularly motivated by the current obesity epidemic, as well as evolutions in the understanding of the role of food and nutrients and the risk of chronic diseases. FDA Commissioner Margaret Hamburg has indicated that the agency hopes the revisions would encourage the food industry to reformulate its products, as did the 2003 rule requiring the declaration of *trans* fat in the Nutrition Facts panel.

We summarize below key provisions of the proposals on which the food industry may wish to comment. FDA invites public comment on its proposed changes, as well as the data and information on which these changes should be based, by June 2, 2014.

Revision of the Nutrition and Supplement Facts Panels

The bulk of FDA's changes appear in its proposed rule on revisions of the Nutrition Facts and Supplement Facts panels. Highlights of these changes include the following:

- **"Added Sugars."** FDA proposes to require a separate declaration of "Added Sugars," on an indented line under the current "Sugars" declaration, which encompasses both added and intrinsic sugars. The agency proposes the declaration of added sugars to enable consumers to implement the 2010 Dietary Guidelines for Americans recommendation to reduce the intake of added sugars (and solid fats). FDA also expressed the view that foods with added sugars are typically less nutritionally dense than those with intrinsic sugars. The agency proposes to define the term "added sugars" as "sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides), syrups, naturally

[1] This proposed rule is available here.

[2] This proposed rule is available here.

occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners."

Added sugars content may 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 would not be required for foods that contain less than 1 gram of added sugars in a serving if no claims are made about sweeteners, sugars, or sugar alcohol content.

Because there are no analytical methods to quantify the amount of added sugars separately from intrinsic sugars, FDA proposes that 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 agency also recognizes the special challenges that may exist where sugars added during processing are subject to fermentation, such as in the production of yeast-leavened breads in which some of the added sugars are consumed by the microorganisms during fermentation. FDA would grant such manufacturers flexibility in determining the amount of added sugars in the finished products, which would need to be documented in records.

These records substantiating the added sugars declaration would need to be kept for a period of at least 2 years after introduction or delivery for introduction of the food into interstate commerce, and would need to be made available to FDA upon request.

- **Dietary fiber.** The proposed rule would define "dietary fiber" as:
  - non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units) and lignin that are intrinsic and intact in plants;
  - isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that FDA has granted be included in the definition of dietary fiber, in response to a petition submitted to FDA under § 10.30 (21 CFR 10.30) demonstrating that such carbohydrates have a physiological effect(s) that is beneficial to human health; or
  - isolated and synthetic non-digestible carbohydrates (with 3 or more monomeric units) that are the subject of an authorized health claim.

  The dietary fiber content would be calculated by subtracting the amount of non-digestible carbohydrates added during processing that do not meet the definition of "dietary fiber." To verify the dietary fiber declaration, FDA proposes that manufacturers be required to keep written records that indicate the amount of non-digestible carbohydrates that do not meet the proposed definition of dietary fiber.

  FDA also proposes, as urged in a citizen petition and prior comments to the agency, that the caloric value of soluble, non-digestible carbohydrates be assigned a general factor of 2 kcal/g rather than 4 kcal/g.

- **Vitamins and minerals of public health significance.** FDA has proposed to update the vitamins and minerals "of public health significance." Current regulations require manufacturers to declare the percent daily values of vitamins A and C, calcium, and iron. Based on the agency's analysis of nutrient inadequacy, FDA proposes to require the declaration of vitamin D and potassium. The declaration of vitamins A and C would become voluntary, while the declaration of calcium and iron would remain mandatory.

  The declaration for all vitamins and minerals would need to include not only the percent daily value, as is currently required, but also their absolute amount per serving. Doing so would help consumers implement recommendations, including from their health care providers, to consume specific amounts of certain vitamins and minerals.

- **Revised Daily Values (DVs).** FDA proposes revisions to the DVs for certain nutrients, including calcium, sodium, dietary fiber, and vitamin D. In particular, FDA would lower the DV for sodium from 2,400 mg to 2,300 mg, in light of recent consensus reports and dietary recommendations.

  While FDA considered setting a DV for calories, the agency ultimately concluded that doing so would not be realistic, given the need to determine a quantitative intake recommendation. FDA therefore will not require (or permit) a percent DV declaration for calories.

- **Trans fat.** The proposed rule continues to require the declaration of *trans* fat on the Nutrition Facts panel, and FDA did not propose to lower the amount below which *trans* fat may be labeled as zero, *i.e.*, less than 0.5 g.

- **Format of the Nutrition Facts panel and related changes.** FDA continues to conduct consumer research to evaluate how changes in formatting will affect a consumer's use and understanding of the Nutrition Facts panel. These results will be published for comment. In the meantime, the proposed rule includes the following changes:

  - Changes to Calories and Serving Size information.

    - The "Calories from fat" declaration would be removed so as not to suggest that these are the only calories about which a consumer need be concerned, and in light of current scientific evidence that shows the type of fat in a food is more important than the total fat content.

    - The "Calories" and "Servings per container" declarations would appear in an increased font size and bold type in order to draw attention to these numbers.

    - The declaration of "Servings per container" would appear above the declaration of the serving size, to emphasize to consumers how many servings are in the package.

    - The "Amount Per Serving" declaration would be revised to "Amount per ___," with the blank filled in using a common household measure, such as "Amount per 1 cup." FDA believes this revision would help consumers better understand the amount of calories and nutrients in each serving.

  - "% [Daily Value]" column. FDA has proposed to shift the % DV column to the left side of the label in order to make this information more prominent to consumers.

  - Footnote. The agency plans to remove the requirement for the footnote table listing the reference values for certain nutrients for 2,000 and 2,500 calorie diets. A replacement footnote has not yet been proposed. FDA continues to conduct consumer research to evaluate how changes in formatting will affect a consumer's use and understanding of the Nutrition Facts panel. The results of this research will be published for comment.

- FDA does not propose significant changes to the Supplement Facts panel but does propose corresponding format changes.

Serving Sizes

This second proposed rule complements FDA's proposed changes to nutrition labels, with its attempt to draw a distinction between foods that are likely to be consumed entirely in one sitting and foods that may be consumed over the course of multiple sittings or shared with other consumers. Highlights from this proposed rule include the following:

- **Single-serving containers and dual-column labeling.** Under the proposed rule, the containers of products containing less than 200 percent of the reference amount customarily consumed (RACC) would be labeled as single-serving containers. In contrast, containers of foods with at least 200 percent and up to 400 percent of the RACC would include a dual-column label: one column would display the nutrition information for the entire container, and the second column would display the preexisting requirement of nutrition information for the serving size based on the RACC.
- **Updated RACCs.** FDA reiterates in the proposal 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 required updating. As a general rule, FDA has proposed changes to RACCs if the NHANES data show median consumption has increased or decreased by at least 25 percent compared to the RACCs published in 1993. New RACCs have been proposed for the following categories of food intended for adults:
  - 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

  Notably, the agency has proposed a new RACC of 12 fluid ounces for sodas, whereas the RACC for juices remains at 8 fluid ounces.
- **Products of concern.** FDA invites comments on the RACCs for certain "products of concern," including: 20 fluid ounce bottles of carbonated beverages, canned soup, snack size packages of potato chips and pretzels (e.g., salty snacks), fruit juice, microwave popcorn, canned chili, shelled nuts, iced tea, TV dinners, energy drinks, canned ravioli, 5-inch pizzas, dairy beverages, pre-packaged lunches, vending machine items, breakfast cereals, macaroni and cheese, cookies, crackers, ice cream, coffee creamer and muffins. Because FDA found that most of these foods did not involve a change in consumption of at least 25 percent, the proposed rule would not change the RACCs for most of these products. The agency also believes that some of the concern about the labeling of these products may be ameliorated by its proposed changes to what constitutes a single-serving container. Nevertheless, the agency specifically requests comments on whether the RACCs for these products should be increased.
- **Implications for nutrient content claims and health claims.** The updated RACCs may carry implications for nutrient content and health claims. 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 significantly such that it now contains more than 3 g fat per RACC. Additionally, an increase in the RACC may trigger the requirement that a referral statement accompany the nutrient content claim if, at the new RACC, the product exceeds the disclosure level for total fat, saturated fat, cholesterol, or sodium. Similarly, a food may be disqualified from making a health claim if its increased RACC would cause it to exceed the disqualification levels for these nutrients.

In sum, the proposed changes to nutrition labeling are not as drastic as some had feared, but the proposals merit careful review and consideration. Stakeholders should consider commenting on areas of interest or concern, or where the proposed rules would benefit from additional refinement.

Covington & Burling LLP 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:

Peter Hutt	202.662.5522	phutt@cov.com
Miriam Guggenheim	202.662.5235	mguggenheim@cov.com
Jeannie Perron	202.662.5687	jperron@cov.com
MaryJoy Ballantyne	202.662.5933	mballantyne@cov.com
Mingham Ji	202.662.5621	mji@cov.com