Multiple New Regulations Push for Healthier Foods

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Earlier this year, we wrote about the spotlight on food labeling in 2016. Halfway through the year, the changes to food and beverage labeling show no signs of slowing down.

The U.S. Food and Drug Administration ("**FDA**") recently released its long-awaited Final Guidance on compliance with the menu labeling rule, as well as its final rules on updated nutrition facts and supplement facts labels and changes to serving sizes of common foods. The FDA has also requested input on the use of the term "natural" and on its standards related to health claims, indicating that we may see future rulemaking in these areas, and it has pressed the industry to cut salt content in food over the next decade. In addition, as of July 1, 2016, Vermont's GMO labeling law will take effect, sending a ripple effect through the food industry as manufacturers adjust their packaging. Finally, local laws—such as Philadelphia's tax on sodas and San Francisco's health warnings on advertisements for soda—continue to shake up affected product manufacturers, even as many wonder whether such laws violate First Amendment rights and challenges to the laws continue.

Menu labeling and the revised nutrition facts panels, supplement facts panels, and serving size rules represent just a few, but perhaps the most significant, new standards for food companies that will take effect in the coming year.

Menu Labeling

The April 2016 release of the FDA's Final Guidance on compliance with the federal menu labeling rule restarted the one-year clock for covered establishments to achieve compliance. The restaurant chain-centric statute was originally part of the 2010 Patient Protection and Affordable Care Act in an effort to combat the growing obesity epidemic in the United States. Six years later, the rule has yet to be enforced. Barring further action from Congress, the timeline is now set and covered establishments should finalize and implement their menu labeling plans by May 2017.

Restaurants, or similar retail food establishments in which the primary business activity is the sale of food to consumers, that are part of a chain with twenty or more locations doing business under the same name, and that offer for sale substantially the same menu items, must provide calorie information for standard menu items, as well as additional nutrition information for such items, upon request. Calories must be displayed clearly and prominently on all menus and menu boards, along with the term "calories" or "cal." Calories for variable menu items (*i.e.*, combination meals) must be displayed in ranges. Calories must be listed per item or per serving on a sign next to foods on display or self-service foods (*i.e.*, a salad bar). Menus and menu boards must also contain a conspicuous, succinct statement indicating suggested daily caloric intake (*i.e.*, "A 2,000 calorie diet is used as the basis for the general nutrition advice; however individual calorie needs may vary."). And the FDA has stated that establishments must have a "reasonable basis" for determining nutrient values, which may involve utilizing nutrient databases, published cookbooks that contain

nutritional information for recipes in the cookbook, nutrition information determined by laboratory analyses, or any other reasonable means.

Updated Nutrition Facts, Supplement Facts, and Serving Sizes

The FDA's final rules on updated nutrition facts and supplement facts labels, as well as serving sizes, take effect in July 2016. Companies with greater than $10 million in sales annually will have until July 2018 to change product labels to comply with the new rules, while companies with less than $10 million in sales annually will have until July 2019 to change product labels to comply with the new rules. The FDA's rules represent the first major overhaul of the nutrition facts panel since its introduction in the early 1990s and aim to reflect the most current nutrition science and consumer habits. The rules also track current trends—for example, removing "Calories from Fat" (since fat was a big focus in the early 1990s) and placing greater focus on sugar by requiring the declaration of added sugars.

Food and supplement manufacturers should consider the far-reaching impact of the new rules. Every food and supplement product label will be affected. Beyond that, however, the FDA has also, for the time being, left other affected regulations, such as those relating to nutrient content claims and health claims, the same. Therefore, products that currently qualify to make such claims may no longer qualify. For example, under current regulations, the recommended daily intake ("**RDI**") for Vitamin C is 60 mg. With the new rule, the FDA has updated the RDI for Vitamin C to 90 mg. Therefore, products that currently may claim that they are "high in Vitamin C" or a "good source of Vitamin C" may no longer qualify for such claims, since the percentages upon which such claims are based remain unchanged in the FDA's other regulations.

Because nutrient content claims and health claims may change for many products, food and supplement companies should also be aware of ancillary material that the FDA may consider part of product labeling, such as information on websites, social media, and blogs. Romance copy (*i.e.*, copy that elaborates on what a product is, what it does, and how a consumer can use it, and often contains implied claims about a product), vignettes, and even product trademarks that are express or implied claims, may also need to change. Food and supplement companies should note the FDA's continued focus on the overall impression given by a product's labeling, suggesting that this will continue to be a hot area for enforcement activity.

Finally, because the new rule indicates the FDA has departed from considering only the properties of a food that can be tested, in a move toward considering the impact of certain ingredients (like added sugar and dietary fiber) on health, the new labeling rule comes with significant recordkeeping requirements. Food and supplement companies should plan early and thoroughly to obtain such information from ingredient manufacturers and should have a strategy in place to protect highly sensitive information, like product formulations. In short, two or three years will pass quickly, so food and supplement companies would be well served to establish working groups now to plan for updates to product labeling and claims.

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