

## CLIENT ALERT

### FDA's Latest Round of Warning Letters Signal that the Agency is Closely Watching and Policing Improper "Healthy" Claims

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The U.S. Food and Drug Administration (FDA) issued a series of Warning Letters in late 2014 to food manufacturers citing the improper use of "healthy" claims on product labeling. In contrast to the term "natural," which – despite pleas from industry, interest groups, and even the courts – FDA has declined to define, agency regulations set forth the conditions under which a manufacturer may claim its food products are healthy. This recent round of regulatory actions demonstrates that the agency intends those rules to have teeth.

#### Requirements for the use of "Health" Claims

Under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act, a food is misbranded if its label expressly or by implication characterizes the level of certain nutrients in a manner that is inconsistent with agency regulations. FDA has set forth specific conditions that manufacturers must meet before they may claim that their products are "healthy" or "healthful" and supportive of choices that are consistent with dietary recommendations. See 21 C.F.R. § 101.65(d)(2). First, the food must meet specific conditions for fat, saturated fat, and cholesterol content. Specifically, companies may use the term "healthy" if, among other things, the product has "low saturated fat" – meaning, the food or substance contains a saturated fat content of 1 gram or less per Reference Amount Customarily Consumed (RACC), and no more than 15 percent of the calories are from saturated fat. Second, the food must meet specific conditions for sodium content. Third, the food must contain at least 10 percent of the Reference Daily Intake or the Daily Reference Value per RACC of one or more of the following nutrients: vitamin A, vitamin C, calcium, iron, protein, or fiber. Finally, the claims must comply with FDA's promulgated declaration and definition requirements. This fits neatly within the general requirements of nutrient content claims as nutrient content claims describe the level of nutrients found in a substance, while health claims link the product's nutrient content to its ability to reduce the risk of diseases or health conditions.

Premier Organics, Minerva Dairy & Sunsweet Growers

With a warning letter to Premier Organics, issued on August 12, 2014, FDA put all manufacturers of coconut products on alert. The company's Artisana Coconut Butter product label included the claims "The Art of Healthy Foods" and "healthy...food..."

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supported by the statement "preserves the life-essential fatty acids, enzymes, vitamins and minerals." FDA objected to the claim because of the amount of saturated fat in the product. According to the letter, the product contained 16 grams of saturated fat per serving, which exceeds FDA's maximum qualifying level for saturated fat.

Two months later, FDA sent warning letters to Minerva Dairy and Sunsweet Growers. The letter to Minerva Dairy, which followed an inspection of the company's cheese and butter manufacturing facility, warned that certain products were misbranded. In particular, it said that Minerva Dairy's All Natural Ilios Greek Yogurt Butter's product label, which bore the claim that it was "A Healthy Butter!" was misleading as the product did not meet the "low saturated fat" requirements. According to the product's Nutrition Facts panel, the product contained 6 grams of saturated fat per serving, which exceeds the maximum 1 gram of saturated fat requirement for "healthy" foods. In addition, the product did not contain the minimum 10 percent of the Reference Daily Intake or the Daily Reference Value per RACC for one or more specified nutrients. FDA also objected to the use of the unauthorized synonym for "healthy"- "good for you" on the product label.

FDA's warning letter to Sunsweet Growers targeted the company's Dark Chocolate PlumSweets product. The product label included statements suggesting that it may be useful in maintaining a healthy diet. In particular, it included the claim "deliciously sweet and healthy diced plums..." in connection with statements such as "Indulge in the Ultimate Antioxidant treat..." FDA asserted that the product did not meet the requirements necessary to make "healthy" claims as it contained 5 grams of saturated fats per serving.

The "healthy" rule is not new, however this latest round of warning letters signals that FDA is watching and policing such claims. The plaintiffs' bar is also likely paying close attention, particularly for claims on foods that do not meet ordinary definitions of "healthy." Notably, the letters referenced above demonstrate that these violations are easily identified upon inspection of the product's Nutrition Facts Label. Food manufacturers must understand that the use of the term "healthy" is, essentially, a nutrient content claim and that products carrying such a claim must comply with the requirements set forth in 21 CFR 101.65(d)(2).

**Crowell & Moring attorneys are actively monitoring the FDAs Enforcement Activities and are available to provide legal guidance on its possible impacts and solutions for your business.**

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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