

CLIENT ALERT

There May Be Hope for That Label Claim, After All: FDA Proposes to Add Additional Non-Digestible Carbs to the Definition of Dietary Fiber

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On March 27, 2019, FDA announced that it intends to grant a citizen petition submitted by MGP Ingredients, Inc. seeking to amend the list of non-digestible carbohydrates that meet the definition of dietary fiber to include cross-linked phosphorylated RS4. In 2016, the FDA published the Nutrition and Supplement Facts Label Rule, which established a definition for the term “dietary fiber.” The definition was intended to ensure that only fibers with a beneficial effect on human health could be declared as dietary fiber on the food label, and includes certain naturally occurring fibers that are “intrinsic and intact” in plants, and seven isolated or synthetic non-digestible soluble and insoluble carbohydrates that FDA has determined have beneficial physiological effects to human health. These effects include:

- Lowering blood glucose.
- Lowering cholesterol levels.
- Lowering blood pressure.
- Increasing frequency of bowel movements (improved laxation).
- Increasing mineral absorption in the intestinal tract.
- Reducing energy intake (for example, due to the fiber promoting a feeling of fullness).

With its announcement, the FDA explained that “[b]ased on available evidence, [it] has determined that the scientific evidence suggests that cross-linked phosphorylated RS4 can help reduce insulin levels following a meal containing a carbohydrate that raises blood glucose levels.”

In addition to cross-linked phosphorylated RS4, FDA also intends to propose that the following non-digestible carbohydrates be added to the definition of dietary fiber:

- Mixed plant cell wall fibers (a broad category that includes fibers like sugar cane fiber and apple fiber, among many others)
- Arabinoxylan
- Alginate
- Inulin and inulin-type fructans
- High amylose starch (resistant starch 2)
- Galactooligosaccharide
- Polydextrose
- Resistant maltodextrin/dextrin

The FDA intends to exercise enforcement discretion to allow manufacturers to include the amount of these additional fibers in the dietary fiber declaration on Nutrition and Supplemental Facts labels until it completes the rulemaking process.

In light of this development, we encourage manufacturers to take a fresh look at proposed label claims that previously did not make the cut due to an insufficient amount of fiber – the product may meet the FDA requirements for making such claims, after all.

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

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