

Using the terms “Organic,” “Healthy,” and “Natural” on Food Labeling

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By Michael H. Cohen

The term “natural” is often used to describe food. The question is – what does the term mean? The same confusion applies to terms like “organic” and “healthy.” The FDA provides little guidance on these issues. Legislation has been proposed that would help clarify these terms but so far, generally, there are no specific laws that define these terms and how the FDA is supposed to monitor and regulate the use of these terms.

FDA authority over labeling food

The Food and Drug Administration has the authority to regulate food based on the Food, Drug, and Cosmetics Act (enacted in 1938) and amended in 1997 by the United States Food and Drug Administration Modernization Act of 1997 (FDAMA).

The claims that can be made on food labels include “*health claims, nutrient content claims, and structure/function claims.*”

REGULATORY COMPLIANCE FOR COSMETICS, NUTRITION, AND CANNABIS COMPANIES – PART 2

Regulatory compliance of cosmetics, diet, and CBD products including FDA misbranding and adulteration, FTC compliance, labeling requirements, and other legal issues.

The use of the term “organic” on food labels

The FDA “*does not regulate the use of the term ‘organic’ on food labels.*”

Any regulation of the term “organic” on food labels is regulated by the National Organic Program (NOP) which is regulated by the US Department of Agriculture (USDA). These regulations are separate from the FDA regulations. “*Food products that are ordinarily under the FDA’s jurisdiction and labeled with organic claims must comply with both USDA NOP regulations for the organic claim and FDA regulations for food labeling and safety.*”

WHY AM I A HEALTHCARE AND FDA LAWYER

At a surface level this is a story of professional development whose roots go deep into my childhood, the fact that I’m I healthcare lawyer.

The use of the term “healthy” on food labels

According to the FDA, foods that use the claim “healthy” must meet specific “nutrient-related criteria.” The FDA is seeking to

update when the term “healthy” can be used so the term comports with current nutrition science and federal dietary guidance. For example, the FDA states that:

“The agency also remains committed to continuing to create a healthier food supply through its recently released guidance to reduce sodium in processed, packaged and prepared foods; to providing consumers with valuable and accessible nutrition and labeling information about the foods they eat; and to providing industry with recommendations on how to use and improve dietary guidance statements on food packaging.”

The FDA issued a proposed rule defining the word “healthy” on September 28, 2022.

The use of the term “natural” on food labels

The FDA did request around 2016 for comments on the use of the term “natural” on food labeling for humans. The FDA stated that the agency was seeking comments based on three Citizen Petitions asking the FDA to define the term “natural” in food labeling and one Petition asking that the term be prohibited. The FDA also sought comments based on federal court comments requesting “*administrative determinations from the FDA regarding whether food products containing ingredients produced using genetic engineering or foods containing high fructose corn syrup may be labeled as ‘natural.’*”

The FDA states that the agency (while it hasn’t announced a specific rule):

“Has considered the term ‘natural’ to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food.”

“This policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA also did not consider whether the term ‘natural’ should describe any nutritional or other health benefit.”

The FDA sought guidance on:

- “Whether it is appropriate to define the term ‘natural?’”
- What the definition of “natural,” should be
- “How the agency should determine appropriate use of the term on food labels.”

FDA PROPOSES UPDATES TO NUTRITION FACTS LABEL ON FOOD PACKAGES

The U.S. Food and Drug Administration today proposed to update the Nutrition Facts label for packaged foods to reflect the latest scientific information.

The Nutrition Facts Label

The FDA, in 2016, updated its Nutrition Facts label requirements on packaged foods and drinks. The new design and information aim to help consumers make better and healthier food choices. The 2016 label requirements address the following issues:

- **The serving size.** The servings per container and how big a serving size is will appear in large, bold font. The serving size (which is not a recommendation of how much to eat) will better reflect what people truly eat and drink.
- **The amount of calories.** The amount of calories in the package will also be in large, bold font. The standard amount of calories (allowing for adjustments based on age, height, weight, sex, and physical activity level) is 2,000 calories each day.
- **The percent daily value.** This value “shows how much a nutrient in a serving of food contributes to a total daily diet.”

Generally low value is 5% or less of a nutrient per serving while 20% is considered high.

- **Nutrient list.** Information that is no longer required includes the calories from fat (because the type of fat is more important) and whether the food or drink has Vitamin A or C. The nutrition label does need to include the amount of added sugars (sugars added to the food process, sweeteners, and “*sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices.*”) The levels of calcium and iron continue to be required.
- **The presence and level of Vitamin D and potassium.** These nutrients can help reduce the risk of osteoporosis and high blood pressure, respectively.

The Food Safety Modernization Act of 2011

The Food Safety Modernization Act (FSMA) of 2011 (not 2023), according to the FDA, is “transforming the nation’s food safety system by shifting the focus from responding to foodborne illness to preventing it.” FDA has:

“Finalized several rules to implement FSMA, recognizing that ensuring the safety of the food supply is a shared responsibility among many different points in the global supply chain for both human and animal food. The FSMA rules are designed to make clear specific actions that must be taken at each of these points to prevent contamination.”

A proposed Food Labeling Modernization Act of 2023

According to Food Navigator, the Food Labeling Modernization Act of 2023 (revised since 2018) has been proposed in both houses of Congress to establish a “single, standard front-of-package nutrition labeling system that would clearly distinguish between produces of greater or lesser nutritional value.”

According to the Centers for Science in the Public Interest, the Food Labeling Modernization Act (FLMA) of 2023 would “align labeling regulations with the latest nutrition science and advance national public health priorities through food labeling policies.” The proposed law aims to provide online information, new health information, and counter misleading claims.

The 2032 proposed FLMA aims to address the following issues:

- **Front-of-Package Labeling.** The proposed law directs the FDA “to establish a standard front-of-package nutrition labeling system for all of the packaged foods it regulates.” This system would complement the Nutrition Facts Label discussed above and “would clearly convey when high levels of sodium, added sugar, or saturated fat (nutrients linked to chronic disease)” are present—comparable to what has already been done in Canada, Child, and other countries.
- **Sodium substitution.** “The FLMA would amend ‘standards of identity’ to allow salt substitution across all packaged foods.” Reducing the amount of sodium intake can lower the risk of hypertension and cardiovascular disease.
- **Online grocery items.** The proposed law would require that Nutrition Facts, ingredient, and allergen information now on packages be available for online grocery items. Consumers can benefit from online information while they’re shopping.
- **Deceptive labeling.** The proposed law aims to address promises that food is healthy when it’s not. For example, “many people don’t know that terms like ‘wheat,’ ‘multigrain,’ and ‘made with whole grain’ tell us nothing about the amount of whole grains in a food.” The new law would require that products that have whole grain claims include the percentage of whole grains in the products.
- **Fruit & Vegetable Claims.** Many products that look or sound like there is a lot of fruit or vegetables only have a minimum amount that don’t “provide the same health benefits as fresh, frozen, or canned produce.”
- **Access to concealed information.** The FLMA will require that the risks of certain food products like too much caffeine (especially for people who are pregnant, take certain medications or supplements, or have certain health conditions) be disclosed. “The FLMA would require disclosure of caffeine content in foods with more than 10 milligrams of caffeine per serving.”

The proposed 2023 FLMA will address other issues including gluten-containing grains. *“Passage of the FLMA will require food labels to reveal potentially harmful ingredients.”*

Food manufacturers and sellers should inform consumers about their products honestly and according to the current laws. Claims such as that a food or drink is “organic,” “healthy,” or “natural,” may be subject to review by the FDA, the USDA, and other agencies – especially if new laws such as the Food Labeling Modernization Act of 2023 are enacted.

Food manufacturers, retailers, and sellers should contact Cohen Healthcare Law Group, PC to review their legal and healthcare compliance requirements including FDA compliance. Our experienced healthcare lawyers advise companies making healthcare claims about compliance laws and regulations issues.

Contact our healthcare law and FDA attorneys for legal advice relevant to your healthcare venture.