Client Alert

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FDA Requests Public Comments on "Natural" Food Labeling

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On November 10, the federal Food and Drug Administration (FDA) announced that it is seeking public comments on use of the term "natural" on food labeling. FDA, "Natural" on Food Labeling (Nov. 10, 2015). The agency explained that its actions were prompted by the "changing landscape of food ingredients and production, and in direct response to consumers who have requested that the FDA explore the use of the term 'natural.'" The announcement came as a surprise since FDA had previously declined requests from consumers, the food industry, and federal judges to define the term.

BACKGROUND

FDA has not regulated the term "natural" on food labels. However, in 1993 it issued an informal "policy," which has two prongs: (i) "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food" (ii) that "would not normally be expected to be in the food." 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993).

In the past few years, there has been a rising tide of food "misbranding" consumer class actions using state consumer protection laws to challenge the health and nutrition labeling and advertising of food products. Many of those class action lawsuits target food products labeled as "Natural," "All Natural," or "100% Natural," but which allegedly contained artificial or synthetic ingredients.

Some of the courts hearing food "misbranding" cases have asked FDA to weigh in on specific uses of "natural" on food labels. For example, in 2013–2014, several federal judges sent letters to FDA asking the agency to opine on whether and under what circumstances food products produced using genetically modified ingredients (GMOs) may be labeled as "natural." FDA declined to opine on the issue, noting that it had other priorities and budgetary constraints. FDA also stated that if the agency were to formally define "natural," it would do so in the context of a public process.

A number of the food "misbranding" lawsuits involving "natural" claims have settled, while others have reached class certification. There is one case—*Brazil v. Dole Food Co.*, Case No. 5:12-cv-01831-LHK (N.D. Cal. filed Apr. 11, 2012)—in which the court granted summary judgment in favor of Dole based on an "All Natural Fruit" mislabeling claim. There, the court agreed with Dole—it is not enough to show that an ingredient is "synthetic" or "artificial," the plaintiff must also prove that the ingredient is not "reasonably to be expected" by consumers. In that case, the products contained citric and ascorbic acids, alleged to be non-natural. That case is currently pending appeal in the Ninth Circuit. (Case No. 14-17480 (9th Cir. filed Dec. 17, 2014).)

CITIZEN PETITIONS ASKING FDA TO DEFINE OR PROHIBIT USE OF "NATURAL" ON FOOD LABELING

In its announcement, FDA noted that it was taking action in part based on four citizen petitions. Three of the citizen petitions—submitted by the Grocery Manufacturers Association (GMA), Sarah Lee Corp., and The Sugar Association—ask FDA to define the term "natural" for use in food labeling. The GMA's citizen petition specifically asks FDA to permit "natural" statements on foods containing GMOs. The fourth citizen petition, filed by Consumers Union, requests that FDA prohibit use of the term "natural" on food labels altogether because it is misleading to consumers.

FDA noted that, while it has had a longstanding policy on the use of "natural" on food labeling, the policy did not address food production methods, such as the use of pesticides, nor did it address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The agency has also has not considered whether the term "natural" should describe any nutritional or other health benefit.

FDA REQUESTS INFORMATION AND COMMENTS ON SPECIFIC ISSUES

In requesting information and comments, FDA has identified a list of specific questions for comments, including:

- Should FDA define, through rulemaking, the term "natural"?
- Should FDA prohibit the term "natural" in food labeling?
- If FDA defines the term "natural," what types of food should be allowed to bear the term "natural"?
- Should only raw agricultural commodities be able to bear the term?
- Should only single-ingredient foods, e.g., bottled water or bagged spinach, be able to bear the term?
- If multi-ingredient foods should be able to bear the term, what type(s) of ingredients would disqualify the food from bearing the term?
- Is the term "natural" on food labels perceived by consumers the same way as the term "organic"?
- If FDA were to revise its policy regarding the use of the term "natural" or engage in rulemaking to establish a regulatory definition for "natural," should certain production practices used in agriculture—for example, genetic engineering, mutagenesis,hybridization, the use of pesticides, or animal husbandry practices—be a factor in defining "natural" ?
- Is the term "natural" on food labels perceived by consumers the same way as "healthy?"
- Should manufacturing processes be considered in determining when a food can bear the term "natural"?
- Should the term "natural" only apply to "unprocessed" foods?
- Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as "natural"?
- What can be done to ensure that consumers have a consistent and accurate understanding of the term "natural" in food labeling to ensure that it is not misleading?

- What are the public health benefits, if any, of defining the term "natural" in food labeling?
- Should "natural" have some nutritional benefit associated with it?
- How might FDA determine whether foods labeled "natural" comply with any criteria for bearing the claim?

Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments, 80 Fed. Reg. 69905, 69908-09 (proposed Nov. 12, 2015) (to be codified at 21 C.F.R. pt. 101), https://www.federalregister.gov/articles/2015/11/12/2015-28779/use-of-the-term-natural-in-the-labeling-of-human-food-products-request-for-information-and-comments. The agency also noted that it is working with the United States Department of Agriculture (USDA) to examine the use of the term "natural" in meat, poultry, and egg products, and is considering areas for coordination between the two agencies. *Id.* at 69905.

FDA will begin accepting public comments on November 12, 2015.

RAMIFICATIONS OF FDA'S ANNOUNCEMENT

FDA's announcement is likely to be welcome news for consumers and the food industry alike. A formal regulation defining "natural" should provide much needed clarity regarding proper use of the term and should help curb future food "misbranding" lawsuits.

A federal definition of "natural" might also help to resolve the conflict over GMO labeling. Vermont's GMO law is set to require labeling by July 2016—if it survives legal challenges. Other states have considered, or conditionally adopted, such laws as well. Regulatory action at the federal government level could preempt these state statutes. A more direct approach to preemption is also pending in the U.S. Senate. In July 2015, The Safe and Accurate Food Labeling Act of 2015 passed the House 275-150; the bill would create a federal standard for the voluntary labeling of foods with GMO ingredients and would preempt state GMO labeling laws.

In the short term, food manufacturers currently facing "natural" mislabeling lawsuits should also consider whether FDA's announcement provides grounds for staying the action under the primary jurisdiction doctrine while the agency considers formal regulatory action.

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