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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FDA Takes A Step Forward On 'Natural' Food Labeling

Law360, New York (November 25, 2015, 10:46 AM ET) -- On Nov. 12, the U.S. Food and Drug Administration began accepting public comments on the use of the term "natural" in the labeling of human foods, "including when, if ever, the use of the term is false or misleading." After years of uncertainty, controversy and litigation surrounding the use of "natural" on food labels, the FDA explains that is now asking for input and comments "because of 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'."

While this initial step does not necessarily mean the FDA will ultimately define "natural," it has important and potentially far-reaching implications for food companies facing related litigation or with products labeled "natural." These companies and other stakeholders have several key questions on their minds after the FDA's unexpected announcement.

Why is the FDA Now Requesting Comments on Using the Term "Natural"?

While most in the food industry were surprised to see the FDA's announcement, many would agree that the FDA simply could not stay out of the conversation any longer.

Although the FDA began a rule making process in the early 1990s to define "natural" on food and beverage labels, the agency ultimately declined to follow through. Instead, the FDA issued nonbinding guidance in 1993 that natural signifies "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 the food."

Due in large part to the lack of a clear FDA definition or policy on "natural," the food industry has seen consumer-fraud lawsuits involving the term increase year over year for the past 10 years. Still, the FDA declined requests to promulgate a formal definition of "natural." For instance, in 2013, three federal judges with separate "natural" labeling-related cases on their dockets asked the FDA for an administrative determination on whether the term can be used on foods with certain ingredients (e.g., ingredients derived from genetically engineered plants).[1] In a January 2014 letter to all three judges, the FDA declined.[2] The FDA issued a similar response to a federal judge in 2010 who sought agency input on whether products with high fructose corn syrup could be labeled "natural."[3]

As the FDA noted, it also received citizen petitions from both industry organizations, such as the Grocery Manufacturers Association and consumer groups, such as the Consumers Union. These petitions ask the agency to define, authorize or limit the use of the term in some way. All argue that defining or establishing a policy on "natural" would provide consistency for consumers and manufacturers.

Though not specifically cited by the FDA, recent legislative developments may have also prompted the agency's action. Vermont's GMO labeling law slated to go into effect July 1, 2016, stipulates that products containing GMOs cannot be labeled as "natural." On the federal level, the House of Representatives passed The Safe and Accurate Food Labeling Act in July 2015 to require the FDA to "regulate" the term on food labeling.[4] The bill has not progressed since its referral to the Senate committee in July 2015. The message is clear: if the FDA won't act on "natural," other governmental entities will.

Does This Mean the FDA Will Define "Natural"?

The food industry and stakeholders should not expect a rule from the FDA on the use of the term "natural" any time soon. The request for comments is not a notice of proposed rule making, or even an advance notice of proposed rule making. If the FDA decides to move forward with rule making, the process will involve many steps over many years.

And the FDA could decline to take any action at all. In its January 2014 letter to the three federal judges, the FDA noted the many issues that the agency would have to consider in creating a definition for "natural," from genetic engineering to certain processing technologies to First Amendment considerations. The FDA stated that as a result, "even if we were to embark on a public process to define 'natural' in the context of food labeling, there is no assurance that we would revoke, amend or add to the current policy, or develop any definition at all."

What Does This Mean for "Natural" Labeling Litigation?

Even though the FDA's final action, if any, on "natural" could be years away, the effects of the FDA requesting public comments are more immediate.

The FDA's announcement provides food companies currently defending "natural" labeling lawsuits with an opportunity to seek a stay or even dismissal of the action under the doctrine of primary jurisdiction. Defendants can argue that because FDA has now demonstrated an interest in potentially regulating or defining "natural," courts should defer to the agency's expertise and not allow a jury to define the term in a potentially conflicting way. Of course, plaintiffs' lawyers will argue that any final agency action is uncertain and, if it does happen, is likely years away, and may not apply retroactively to their clients' claims in any event. How courts receive these motions remains to be seen. But some California judges in on the front lines of "natural" litigation may not want to pass up the opportunity to invoke primary jurisdiction to remove "natural" class action cases from their crowded dockets.

In addition to affecting existing cases, the FDA's announcement may also cause a sharp downward trend in future litigation challenging "natural" claims. Faced with a potential primary jurisdiction challenge, plaintiffs' lawyers will likely shift their focus to challenging label terms and claims other than "natural." That dynamic is already underway, as "natural" has been removed from many food labels and the FDA's announcement will only accelerate it.

What Does This Mean for Food Labels?

In the short term, the FDA's request for comments creates additional uncertainty around use of "natural" on food labels. Until the FDA takes further action, companies still face risks associated with using "natural."

Brands with existing "natural" labeling may want to evaluate the continued use of the term. Though a definition, if any, may be years away, is there a chance the product will not meet it? Does it make sense to begin transitioning to new label formats and claims? Likewise, now may not be the best time to add "natural" to a label when the claim may later have to be removed.

But in the long term, an FDA definition of "natural" would be a boon to producers of FDA-regulated food products. With a formal FDA definition or policy on "natural" in place, plaintiffs' claims seeking to impose some other standard or definition would be preempted. That's already the case for U.S. Department of Agriculture-regulated products.[5]

Meat, poultry and egg labels that fall under the USDA's jurisdiction likely will not be affected by any action by the FDA in this area. But some stakeholders hope the FDA follows the USDA's lead in "natural" labeling, with an enforced definition or even some form of an approval process similar to the USDA's labeling regime. The FDA says that it is working with the USDA Agricultural Marketing Service and Food Safety and Inspection Service to examine the use of the term "natural" in meat, poultry and egg products, and "are considering areas for coordination between the FDA and the USDA."

What Should We Expect From the Comments Process?

At the highest level, the FDA is seeking comments on what it should do to regulate "natural" — whether it should prohibit the term altogether, or define "natural" in a rule, and, if so, how the agency should determine whether foods labeled "natural" comply with the rule.

But recent litigation, legislation and consumer blogs give a clear indication that "natural" implicates all aspects of food production, from farm to store shelves, all of which stakeholders can expect to see in the comments process. For example, as seen in Vermont's GMO labeling law, as well as recently filed class action lawsuits, whether foods that are derived from or contain plant material grown from genetically engineered seeds can be labeled "natural" continues to thrive as a hot-button issue. Recent class action lawsuits and consumer blogs have also focused on whether a product can be labeled "natural" when it contains certain ingredients that undergo extensive processing or those ingredients are themselves derived from materials alleged to be "unnatural."

In its notice, the FDA asks for information and public comment on these and a number of other specific questions reflective of the type of issues that the food industry has seen in lawsuits and consumer comments, such as:

- Use of "natural" compared to "organic"
- Manufacturing processes, such as curing, marinating, freezing, canning, fermenting, pasteurizing or irradiating
- Agricultural practices, including the use of pesticides and animal husbandry practices
- Whether "natural" implies or is synonymous with "healthy"

No term has created more litigation for the food industry in recent years than "natural." At the same time, "natural" on food labels has been subject to heightened consumer scrutiny and social media discussion. As a result, we can expect to see a high level of participation in the comments process from a variety of stakeholder perspectives.

The FDA is accepting public comments until Feb. 10, 2016. The industry and other stakeholders should monitor and take an active role in the comments process for this important issue. To electronically submit comments to the docket, visit this page and type FDA-2014-N-1207 in the search box.

—By Sarah L. Brew and Courtney A. Lawrence, Faegre Baker Daniels LLP

Sarah Brew leads Faegre Baker Daniels' food litigation and regulatory practice and is based in Minneapolis.

Courtney Lawrence is an associate ine Faegre Baker Daniels' Minneapolis office.

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[1] See Order Granting Motion to Dismiss in Part (Dkt. No. 37) and For Referral to The United States Food and Drug Administration, Cox v. Gruma Corp., No. 4:12-cv-6502 (N.D. Cal. July 11, 2013) (Dkt. No. 68); Order Granting in Part and Denying in Part Defendant's Motion to Dismiss Second Amended Class Action Complaint and Staying Matter, Barnes v.Campbell Soup Co., No. 3:12-cv-05185 (N.D. Cal. July 25, 2013) (Dkt. No. 55); Order, In ReGeneral Mills Inc. Kix Cereal Litigation, No. 2:12-cv-00249 (D.N.J. Nov. 1, 2013) (Dkt. No. 92).

[2] See Letter from Leslie Kux, Assistant Commissioner for Policy, to the Honorable Yvonne Gonzales Rogers, U.S. District Court, Northern District of California, the Honorable Jeffrey S. White, U.S. District Court, Northern District of California and the Honorable Kevin McNulty, U.S. District Court, District of New Jersey (Jan. 6, 2014).

[3] See Order for Referral to United States Food and Drug Administration, Coyle v. Hornell Brewing Co., No. 1:08-cv-02797 (D.N.J. June 25, 2010) (Dkt. No. 118).

[4] The Safe and Accurate Food Labeling Act, H.R. 1599, 114th Cong. (July 24, 2015).

[5] See, e.g., Kuenzig v. Hormel Foods Corp., et al., No. 12-11180 (11th Cir. Feb. 1, 2013), aff'g 2012 U.S. Dist. LEXIS 102746 (M.D. Fl. Sept. 12, 2011) (dismissing state law claims that lunch meat labels were false or misleading because the labels were approved by the USDA and therefore preempted by the FMIA and the PPIA).