

## ALERTS

### Food, Drug & Device Law Alert - Will FDA Finally (And Officially) Define “Natural?”

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Less than two years ago, we reported [here](#) that the Food and Drug Administration (FDA) had issued a letter to three federal district court judges declining the courts’ requests to adopt a definition of “natural” or to state whether the terms “natural” or “all natural” can be used to refer to foods containing genetically-modified organisms (GMOs) to help resolve pending consumer class actions over the term. In an apparent about-face, the FDA recently issued a request for comments on several questions related to the definition of “natural” for human food labeling.

Specifically, the FDA asks for information and public comment on questions such as:

- Whether it is appropriate to define the term “natural,”
- If so, how FDA should define “natural,” and
- How FDA should determine the appropriate use of “natural” on food labels.

In the notice requesting comments, FDA states that it is taking this action in part because it received three Citizen Petitions asking it to define “natural” for use in food labeling and one Citizen Petition asking that the agency prohibit use of the term “natural” on food labels.

As reported [here](#), previously the FDA had a “policy” on the definition of “natural” set forth in 58 Federal Register 2302 (January 6, 1993) (Notice). Interestingly, at page 2407 of the Notice, the FDA expressly disclaimed any intention to adopt a definition of natural, stating: “Although the use of the term ‘natural’ on the food label is of considerable interest to consumers and industry, FDA’s intent was not to establish a definition for ‘natural’ in this rulemaking.” The FDA further stated:

The agency will maintain its current policy ... not to restrict the use of the term “natural” except for added color, synthetic substances, and flavors as provided in [21 C.F.R.] § 101.22. Additionally, the agency will maintain its policy ... regarding the use of “natural,” as meaning 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.

This “current policy” language has incorporated into the warning letters in the past as the basis for alleged violations of the Food, Drug & Cosmetic

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The policy, however, did not address (1) food production methods, such as the use of pesticides, or (2) 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 began accepting public comments on November 12. The FDA docket number is FDA-2014-N-1207.

For more information, contact the Barnes & Thornburg attorney with whom you work or Lynn Tyler at (317) 231-7392 or [lynn.tyler@btlaw.com](mailto:lynn.tyler@btlaw.com) or Alicia Raines at 317-231-7398 or [alicia.raines@btlaw.com](mailto:alicia.raines@btlaw.com).

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