

## MEMORANDUM

**From:** Steven B. Steinborn  
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**Date:** November 11, 2015

**Re:** **FDA Requests Comment on “Natural” Claims**

The U.S. Food and Drug Administration (FDA) is inviting public comment on the use of the term “natural,” an issue that has come to the forefront in the context of private litigation and surrounding developments. The request comes in response to three citizen petitions asking that the agency define the term “natural” for use in food labeling, one petition requesting that FDA prohibit the term “natural” on food labels, and requests from federal courts stemming from private litigation asking that FDA issue an administrative determination addressing whether foods containing genetically engineered ingredients or high fructose corn syrup may be labeled as “natural.”

FDA also plans to work with the U.S. Department of Agriculture’s (USDA’s) Food Safety and Inspection Service (FSIS) to examine the use of “natural” claims related to meat, poultry, and egg products, as well as to identify areas of coordination between FDA and USDA. Comments are due February 10, 2016. <sup>1/</sup>

### Background

FDA first considered “natural” in tripartite hearings held along with USDA and the Federal Trade Commission in the late 1970s. USDA subsequently adopted a definition in the early 1980s, while FDA revisited the issue in the early 1990s. FDA concluded that the comments submitted at that time did not provide the agency with a specific direction to follow in developing a formal definition in a regulation. Instead, FDA stated that it would maintain its existing policy, under which the agency would not restrict the use of the term “natural” except for added color, synthetic substances, and flavors as provided in 21 C.F.R. § 101.22. In addition, FDA would continue to interpret the term “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.” <sup>2/</sup> This policy did not address food production or manufacturing methods.

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<sup>1/</sup> Comments should be submitted to Docket No. FDA-2014-N-1207.

<sup>2/</sup> Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed Reg. 2302, 2407 (Jan. 6, 1993). FDA has also stated that, in the context of bottled water, whether a specific product may be labeled “natural” turns on whether or not it was subject to only “minimal processing.” Beverages: Bottled Water, 60 Fed. Reg. 57076, 57099 (Nov. 13, 1995).

Since then, scrutiny of “natural” claims has increased substantially, and the agency has received four citizen petitions requesting that FDA take action addressing the use of the term. The scope of these requests varies significantly. The Grocery Manufacturers Association, for example, submitted a narrow request that FDA issue a regulation stating that is not false or misleading to label a food “natural” or with similar terms solely because a food is or contains a food derived from biotechnology. On the opposite end of the spectrum, the group Consumers Union submitted a petition requesting that FDA issue a regulation declaring that the term “natural” and similar terms are vague and misleading and should not be used. The group offered survey data it says suggests that many consumers expect the term “natural” to “mean much more than it does.” <sup>3/</sup>

### **FDA’s Request for Comment**

FDA seeks comment on a broad range of issues related to how (or if) it should regulate the use of “natural,” including the following.

- Whether a definition of “natural” should exclude certain foods or foods containing certain ingredients and whether it should take into account issues such as production practices (e.g., genetic engineering, pesticide use, animal husbandry practices), manufacturing practices (e.g., drying, curing, pasteurization, fermentation, irradiation, hydrolysis), or the manner in which an ingredient is produced (e.g., synthetic processing).
- Data or other information on whether consumers associate, confuse, or compare “natural” with “organic.” Similarly, whether this issue arises between “natural” and “healthy.”
- Whether “natural” should only apply to “unprocessed” foods. If so, how “processed” and “unprocessed” should be defined.
- Whether synthetic forms of vitamins and minerals should be allowed in a “natural” food.

FDA encourages interested parties to provide the bases for any positions taken.

### **Implications**

Whether FDA finally will establish clear boundaries dictating the use of “natural” is difficult to predict. It is clear that the issue is very much in play as a result of the request for comments. Moreover, the breadth of the questions FDA has posed indicates the agency is considering possibly moving beyond its current policy, focusing on whether a food contains artificial or synthetic ingredients, to include more extensive considerations such as type of food (e.g., single ingredient foods, multi-ingredient foods, raw agricultural commodities), production techniques, and nutritional benefits.

Coordination with USDA is sensible given that FSIS issued an Advanced Notice of Proposed Rulemaking in September 2009 on many of the same issues relating to “natural.” FSIS has taken no formal action since then. Efforts to arrive at a cohesive, single “natural” definition date back to the

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<sup>3/</sup> FDA also received separate petitions from Sara Lee Corp. and the Sugar Association. The petition from Sara Lee asks FDA to adopt a unified policy for “natural,” to account for several factors such as the use of artificial flavors and coloring ingredients, and the Sugar Association petition requests that FDA define “natural” based on FSIS’s definition in its Food Standards and Labeling Policy Book.

1970s. Interested parties should view this FDA action as an important opportunity to be heard on a subject that will attract comments from a broad spectrum of stakeholders.

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Please let us know if you have questions or if we can be of any assistance.