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Via electronic submission (www.regulations.gov)

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Food and Drug Administration Docket No. FDA-2014-N-1207:
Use of the Term "Natural" in the Labeling of Human Food Products,
Request for Information and Comments;
80 *Fed. Reg.* 69905 (November 12, 2015), and Extension of Comment Period80 *Fed. Reg.* 80718 (December 28, 2015)

To Whom It May Concern:

On behalf of the American Spice Trade Association (ASTA), we appreciate the opportunity to submit comments in response to the US Food and Drug Administration's (FDA) request for information and comments on use of the term "Natural" in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering, 80 *Fed. Reg.* 69905 (November 12, 2015). In response to multiple requests, the FDA extended the comment period for public input until May 10, 2016, 80 *Fed. Reg.* 80718 (December 28, 2015).

Introduction to the American Spice Trade Association

ASTA was established in 1907 to provide representation for the American spice trade. Its members include companies involved in all aspects of the spice trade – importing, growing, processing, and marketing at the wholesale and retail levels. On behalf of its members, ASTA works with federal and state regulators, including FDA, as well as legislators, to assist its members in addressing a variety of technical issues to help members provide an adequate supply of safe and wholesome spices for their industrial, food service and consumer customers.

Executive Summary

The Food and Drug Administration (FDA) recently established a docket to receive information and comments regarding the use of the term "natural" in the labeling of human food products. FDA is taking this action because it has received multiple citizen petitions requesting that FDA take some action regarding the use of the term "natural" in food labeling. Additionally, the agency received requests from Federal court judges, as a result of litigation between private parties, to issue administrative determinations regarding whether food products containing ingredients produced using genetic engineering or foods containing high fructose corn syrup may be labeled as "natural." Although FDA has not previously promulgated a rule defining the term "natural" for use in the labeling of food products, FDA has previously invited public comments on the term, which culminated in the development of an agency policy regarding the use of the term "natural" in the labeling of food products.

FDA's longstanding policy for the use of the term "natural" on food labels was first articulated in the preamble of the proposed rule to implement the Nutrition Labeling and Education Act of 1990 (NLEA).[1] FDA's policy does not prohibit the use of the term "natural" on food product labels, but the policy does describe the agency's current thinking with respect to "natural" labeling of finished food products. According to its policy, FDA interprets the term "natural" as meaning that "nothing artificial or synthetic (including 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."[2] FDA recently reiterated this policy in a 2014 letter to three federal judges who, as a result of interpretative and primary jurisdiction issues present in three separate private federal cases, requested FDA make an administrative determination regarding the use of the term "natural" in the labeling of food products.

Although FDA has had a longstanding policy regarding the use of the term "natural" on the labels of human food[3], there remains a great deal of uncertainty among consumers as to what "natural" labels on food products mean or signify. Recent events have prompted FDA to revisit the issue of defining the term to provide clarity both to consumers and industry. ASTA generally supports FDA's intent to investigate whether it should define the term "natural" through rulemaking. ASTA is pleased to provide the following comments regarding spices, and specifically requests that, should FDA define "natural" for use in labeling of food products, spices should continue to be permitted in foods labeled as "natural." Additionally, as published in the Federal Register, FDA posed a series of questions regarding the use of the term "natural" in labeling food products. ASTA is pleased to provide responses to those questions relevant to the spice industry.

Spices are natural under current FDA policy and should be permitted in food products labeled as "natural"

"Spice" is defined in the Code of Federal Regulations at 21 CFR Sec. 101.22(a)(2) as:

[1] 56 *Fed. Reg.* 60421 (Nov. 27, 1991).
[2] 58 *Fed. Reg.* 2302 at 2407 (1993).
[3] *80 Fed. Reg. 69906 (Nov. 12, 2015).*

> "any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. They include spices listed in 182.10 and part 184 of this chapter, such as the following: Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamon, Celery seed, Chervil, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Fennel seed, Fenugreek, Ginger, Horseradish, Mace, Marjoram, Mustard flour, Nutmeg, Oregano, Paprika, Parsley, Pepper, black; Pepper, white; Pepper, red; Rosemary, Saffron, Sage, Savory, Star aniseed, Tarragon, Thyme, Turmeric. Paprika, Turmeric, and Saffron or other spices which are also colors, shall be declared as "spice and coloring" unless declared by their common or usual name."

Substances declared as "spice" on the ingredient statement of a food product must comply with the specific criteria set forth in 101.22(a)(2). In order to be labeled as a spice, the substance must meet each element of the regulatory definition: 1) be derived from an aromatic vegetable substance; 2) serve a seasoning technical effect in food; and, 3) retain the volatile oil or other principle flavoring component. The plain language of FDA's promulgated "spice" definition is concise and gives consumers a clear signal that spice has been added to food, which ensures that consumers are not misled as to the addition of spice. Additionally, spices are well recognized by consumers as being derived from vegetable material, and as a result, there is little confusion among consumers that spices are a natural product.

In addition to being familiar with spices added to multi-ingredient packaged foods, consumers have a deep relationship with spices as essential elements to their own at-home recipes. Consumers clearly recognize spices as natural and use them on a daily basis in their cooking at home. This tangible consumer experience with spices is an assurance that consumers recognize the "naturalness" inherent in spices. As a result, should FDA ultimately decide to define the term "natural" as it would be used in the labeling of food products, FDA should unequivocally permit the addition of "spices" to "natural" food products. Such regulatory action would not only be consistent with the agency's decades-long policy on the term "natural," but it would be appropriate since spices are derived from vegetable material.

ASTA agrees that there is confusion in the marketplace pertaining to labeling of food as "natural," and in the absence of a regulatory definition, consumers are likely to interpret the term in different ways. Defining the term "natural" for labeling purposes would provide clarity for consumers and provide a clear standard for industry to meet. However, ASTA maintains that any definition of "natural" should be clear, consistent with current policy and permit the addition of "spice" to "natural" food products.

ASTA's responses to FDA's specific requests for comment and information

Within FDA's Notification for Comments regarding the use of the term "natural" in the labeling of human food, the agency posed a series of specific questions for public comment.[4] ASTA is responding to those questions that are relevant to the spice industry.

[4] See 80 Fed. Reg. 69905 at 69908-69909 (Nov. 12, 2015).

- **Should we define, through rulemaking, the term "natural?" Why or why not?**

  Yes, ASTA believes that FDA should, through notice and comment rulemaking, define "natural" for use in the labeling of human food products. Available market data suggests that American consumers are making buying decisions based on their desire for "natural" foods. Consumers seek out "natural" food options beyond raw produce and expect to have "natural" options in the center of the grocery store as well. In response to this growing consumer demand, food manufacturers have worked to develop a wide variety of "natural" food options, but there exists some disagreement, even among consumers, about what "natural" means when used on finished food product labels. Although the regulated food industry can look to FDA's current policy on the use of the term "natural" when developing and marketing "natural" food products, the policy does not provide sufficient specificity to help food manufacturers develop and manufacture products that consumers will consistently understand and trust to be "natural."

  By defining the term "natural" as it may be used in labeling food products through formal notice and comment rulemaking, FDA can finally move beyond policy and establish legal parameters to the use of the term "natural" in food labeling. Although FDA's policy may provide some insight into the agency's thinking regarding "natural" labeling and the type of "natural" claims that might render a product misbranded under §343 of the FD&C Act, without formal rulemaking to legally define the term "natural," there may continue to exist a disparity between what food manufacturers understand to be the consumer's expectations for "natural" foods and the consumers' actual perceptions as to what food labeled as "natural" means. Without a regulatory definition, private litigation abounds as consumers and an eager plaintiff's bar challenge "natural" food labeling under various state unfair competition statutes. We cannot continue to rely on the federal court system to serve as an arbiter. Instead, FDA should act and engage in notice and comment rulemaking to define the term "natural" for use in the labeling of human food. If FDA does define the term "natural," FDA should permit "spice" to be added to food products labeled as "natural."

- **Should we prohibit the term "natural" in food labeling? Why or why not?**

  No, FDA should not prohibit the term "natural" in food labeling. Although there currently exists some disagreement as to the meaning of the term "natural" when used on food labels, consumers nonetheless continue to look for "natural" food options. ASTA believes that FDA should, through rulemaking, define the term "natural" for use in food product labeling and any such definition should permit "spice" to be used in or added to "natural" food products.

- **If we define the term "natural," what types of food should be allowed to bear the term "natural?"**

  ASTA requests that FDA define the term "natural" for use in food labeling such that any

food which includes “spice” may qualify for “natural” labeling.

- **Should only single ingredient foods, e.g., bottled water or bagged spinach, be able to bear the term? Why or why not?**

  In addition to single ingredient foods, which includes spices sold at retail for direct consumer use, consumers appear to search for and purchase multi-ingredient packaged foods labeled as “natural.” As such, FDA should consider a definition of “natural” to include such foods.

- **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?**

  In order to ensure that “natural” food labeling is not misleading to consumers, FDA should embark on rulemaking to formally define “natural” for use in food product labeling. ASTA supports a clear definition of “natural” food that permits the addition of “spice” to “natural” food.

Conclusion

We appreciative the opportunity to provide input as FDA considers whether, through rulemaking, to define “natural” for use in food labeling.

Sincerely,

Cheryl Deem
Executive Director