

FDA EXTENDS PUBLIC COMMENT PERIOD ON PROPOSAL TO DEFINE “NATURAL” FOR FOOD LABELING PURPOSES

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The FDA has extended the deadline for receiving public comments regarding the need for promulgation of regulations relating to the food and beverage industries’ use of the term “natural” on food labeling. The public comment period will end on May 10, 2016, rather than the end of February, as initially communicated by the agency.

BACKGROUND

Currently, three federal agencies, the FDA, USDA and TTB deal with food or beverage products that are labeled as “natural.” To date, none has formally defined the term “natural,” although each agency has offered limited guidance on the proper use (or misuse) of the term.

The FDA

To date, the US Food and Drug Administration has not engaged in rulemaking to establish a formal definition for the term “natural.” However, the agency asserts that it has a long-standing policy concerning the use of the term “natural” in human food labeling, generally considering the term to mean “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 that food.” According to the FDA:

From a food science perspective, it is difficult to define a food product that is ‘natural’ because the food has probably been processed and is no longer the product of the earth. That said, FDA has not developed a definition for use of the term natural or its derivatives. However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.¹

FDA has stated in published comments that this informal policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. FDA also has yet to consider whether the term “natural” should describe any nutritional or other health benefit.

The USDA

The US Department of Agriculture deals with the term “natural” in the context of its regulation of “organic” foods. USDA has never defined “natural” in a formal process applicable to all foods; rather, it addresses the subject on a case-by-case basis, primarily to distinguish “natural”

¹ Accessible online at TTB’s Website: <http://www.fda.gov/aboutfda/transparency/basics/ucm214868.htm> (last accessed on January 19, 2016).

products from those labeled as “organic,” which the department spent years defining.² For example, according to the USDA meat, poultry or eggs labeled as “natural” means:

NATURAL:

A product containing no artificial ingredient or added color and is only minimally processed. Minimal processing means that the product was processed in a manner that does not fundamentally alter the product. The label must include a statement explaining the meaning of the term natural (such as "no artificial ingredients; minimally processed").³

As required by USDA, meat, poultry, and egg products labeled as “natural” must be minimally processed and contain no artificial ingredients. However, the natural label does not include any standards regarding farm practices and only applies to processing of meat and egg products. There are no standards or regulations for the labeling of natural food products if they do not contain meat or eggs.

The TTB

The US Alcohol and Tobacco Tax and Trade Bureau is responsible for regulating alcohol beverages. Through its predecessor, the US Bureau of Alcohol, Tobacco and Firearms, the agency issued ATF Ruling 85-4: LABELING AND ADVERTISING ALCOHOL BEVERAGES AS "NATURAL." While the bulletin does not actually define the term “natural,” it does describe when TTB takes no exception to its use:

- (1) Any grape fruit, citrus or agricultural **wine** may be designated “natural” if it is made without added alcohol or brandy...No other type of wine may be designated as “natural.”
- (2) A **distilled spirit** may be designated as “natural” if is solely the result of distillation, with or without mingling of the same class and type of spirits or simple filtration which does not alter the class or type of the product.
- (3) A **malt beverage** may be designated “natural” if it is made without adjuncts (additives) other than those additives which do not remain in the finished product, either by precipitating out or by combining with other components of the product and the resulting compound precipitates or is filtered out.⁴

² In 2000, the USDA finalized the regulations relating to the National Organic Program (NOP) at 7 CFR Part 205. These rules provide new standards for the production, handling, processing, labeling, and marketing of products labeled with organic claims.

³ Accessible online at the Food Safety Inspection Service’s section of the USDA’s Website: <http://www.fsis.usda.gov/wps/wcm/connect/fsis-content/internet/main/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/meat-and-poultry-labeling-terms/meat-and-poultry-labeling-terms> (last accessed on January 19, 2016).

⁴ Accessible online at TTB’s Website: http://www.ttb.gov/industry_circulars/archives/1985/85-04.html (last accessed on January 19, 2016).

THE IMPORTANCE OF DEFINING “NATURAL”

The question of when a product can be labeled as “natural” take on increasing importance with the proliferation of mislabeling lawsuits related to food products, and now even alcohol beverages. Over the last few years, plaintiffs have become very aggressive in suing food and beverage manufacturers asserting that labels characterizing the products as “natural” are misleading – either because of the means of production or the ingredients contained in the products.

In particular, plaintiffs are going after claims that a product is "all-natural" or "100 percent natural." Plaintiffs contend such claims misrepresent the health benefits or ingredients of the products in ways that allow the manufacturers to charge a premium to consumers.

Food and beverage mislabeling lawsuits allege a broad range of violations of express labeling regulations and deceptive marketing practices. This surge in class action litigation has included attacks on respected, well known brands, such as:

- **Dole’s** fruits (allegedly false use of the term “all natural” because packaged fruits contain ascorbic acid and citric acid);
- **Snapple Juice, Healthy Choice Pasta Sauce** and **Arizona Beverage Co. Iced Teas** (allegedly falsely labeled as "natural," but contain high-fructose corn syrup);
- **Frito-Lay’s Rolled Gold Pretzels** (alleging pretzels contain unnatural ingredients (including niacin, riboflavin, folic acid, and ammonium bicarbonate);
- **Tostitos, Sun Chips, Naked Juice** beverages, and **Wesson Vegetable Oil** (allegedly falsely labeled as "natural," but contain "genetically modified organisms");
- **Blue Diamond Almond Milk** (allegedly false for being labeled “all natural” even though the product contains a synthetic ingredient, potassium citrate);¹
- **Tropicana Orange Juice** (allegedly falsely advertised as natural but scientifically engineered in laboratories);
- **Ben & Jerry’s Ice Cream** (allegedly misrepresented ice cream containing “Dutch” or “alkalized” cocoa as “all natural” because the alkalized cocoa used is processed with potassium carbonate, a man-made synthetic ingredient);
- **Fiber One** (allegedly falsely represented as containing natural fiber, but instead contains a chemically extracted substance called inulin);
- **Lipton Tea** and **Hershey Chocolate** (allegedly falsely represented health benefits of flavonoid antioxidants);

- **Kellogg Co.’s Kashi** branded snack foods and cereals (allegedly falsely labeled as "nothing artificial," but contain synthetic ingredients);
- **Splenda** no-calorie artificial sweetener (allegedly claimed fortified with vitamins, antioxidants or fiber, but the product purportedly does not deliver health benefits);
- **Chobani Yogurt** (allegedly misleadingly identified sugar as "evaporated cane juice");
- **Nestle Coffee Mate Creamer** (allegedly mislabeled as containing "0 grams trans-fat").

The alcohol beverage sector is not immune to these types of mislabeling claims. For example, in *Langendorf v. Skinnygirl Cocktails*, the plaintiff alleged that **Skinnygirl Margarita**, a pre-mixed alcohol beverage sold to on-premises retailers, contains the non-natural preservative sodium benzoate, and therefore its “all natural” label is false and misleading.⁵

THE FDA’S DECISION TO CONSIDER RULEMAKING

As litigation increases, the need for defining the term “natural” has grown. Because of this need, FDA is requesting comment on the use of the term natural in the labeling of human food in direct response to consumers who have requested that FDA explore the use of the term. According to the agency:

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,” the agency is asking the public to provide information and comments on the use of this term in the labeling of human food products.

FDA is taking this action in part because it received three Citizen Petitions asking that the agency define the term “natural” for use in food labeling and one Citizen Petition asking that the agency prohibit the term “natural” on food labels. The agency also notes that some federal courts, as a result of litigation between private parties, have requested administrative determinations from FDA regarding whether food products containing ingredients produced using genetic engineering or foods containing high fructose corn syrup may be labeled as “natural.”

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

- Whether it is appropriate to define the term “natural?”

⁵ On October 30, 2014, the Northern District of Illinois declined to certify a class of consumers who had purchased the Skinnygirl Margarita product since 2009. First, the court found the class lacked ascertainability because Skinnygirl Cocktails were never sold directly to consumers, and plaintiffs failed to show how class membership could be verified by the dates of purchase, the locations of retail establishments, and the frequency, cost, and quantity of purchases. Further, the court noted that there was no evidence to show that the potential class members would not have bought the product based on “the presence of a small quantity of sodium benzoate.” *Langendorf v. Skinnygirl Cocktails, LLC*, --- F.R.D. ---, 2014 WL 5487670 (N.D. Ill. Oct. 30, 2014):

- If so, how the agency should define “natural?” and
 - How should the agency determine appropriate use of the term on food labels?
- Anyone interested in submitting a public comment regarding the administrative definition of “natural” can direct their input to the FDA. Comments electronically or by mail.

For electronic submissions, go to docket folder FDA-2014-N-1207 on *Regulations.gov*, which is accessible at <http://www.regulations.gov/#!submitComment;D=FDA-2014-N-1207-1827>

For submissions by mail, use the following address:

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

Be sure to include docket number FDA-2014-N-1207 on each page of your written comments.

The comment period closes May 10, 2016.