4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2014-N-1207]

Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of request for comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the 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. We are taking this action in part because we received three citizen petitions asking that we define the term "natural" for use in food labeling and one citizen petition asking that we prohibit the term "natural" on food labels. We also note 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." We are working with the United States Department of Agriculture (USDA) Agricultural Marketing Service and Food Safety and Inspection Service to also examine the use of the term "natural" in meat, poultry, and egg products, and are considering areas for coordination between FDA and USDA. We invite public comment on the term "natural" in the context of food labeling and on specific questions contained in this document.

DATES: Comments must be received on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include Docket No. FDA-2014-N-1207 for "Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Loretta Carey, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2371.

SUPPLEMENTARY INFORMATION:

I. Background

A. What Has Been FDA's Position Regarding the Use of the Term "Natural?"

Under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(a)(1)), a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. Section 201(f) of the FD&C Act (21 U.S.C 321(f)) defines the term "food" to mean articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such article. Subject to certain exceptions, dietary supplements are generally considered to be foods under the FD&C Act (21 U.S.C. 321(ff)). Section 201(n) of the FD&C Act (21 U.S.C. 321(n)) provides that labeling is misleading if, among other things, it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use

of the food to which the labeling relates under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual. Section 201(m) of the FD&C Act defines "labeling" as all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

We have a longstanding policy for the use of the term "natural" on the labels of human food. We previously considered establishing a definition for the term "natural" when used in food labeling. In the preamble of a proposed rule we published in the Federal Register (56 FR 60421, November 27, 1991), we stated that the word "natural" is often used to convey that a food is composed only of substances that are not manmade and is, therefore, somehow more wholesome. We also said that we have not attempted to restrict use of the term "natural" except for added color, synthetic substances, and flavors under § 101.22 (21 CFR 101.22) (56 FR 60421 at 60466). Further, we said that we have considered "natural" to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there (56 FR 60421 at 60466).

We also noted that the term "natural" is used on a variety of products to mean a variety of things. Because of its widespread use, and the evidence that consumers regard many uses of this term as non-informative, we said, back in 1991, that we were considering establishing a definition for this term (56 FR 60421 at 60466). We said that we believed that defining the term "natural" could remove some ambiguity surrounding use of the term that results in misleading claims (56 FR 60421 at 60466).

We invited comments on several questions, including whether we should establish a meaningful definition for "natural" so that this term would have a common consumer understanding, and whether it should prohibit "natural" claims entirely on the grounds that they

are false or misleading (56 FR 60421 at 60467). In the preamble to the subsequent final rule, we noted that we had received many comments on the subject, but that "[n]one of the comments provided FDA with a specific direction to follow for developing a definition regarding the use of the term 'natural.' " (58 FR 2302 at 2407, January 6, 1993). We stated that at that time we would not be engaging in rulemaking to define "natural," but that we would maintain our policy not to restrict the use of the term "natural" except for added color, synthetic substances, and flavors. We further stated that we would maintain our policy 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" (58 FR 2302 at 2407).

When we established our policy concerning the use of the term "natural," as described previously in this document, it was not intended to address food production methods, such as the use of genetic engineering or other forms of genetic modification, the use of pesticides, or the use of specific animal husbandry practices, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. Furthermore, we did not consider whether the term "natural" should describe any nutritional or other health benefit.

B. What Recent Events Prompted FDA to Request Comment?

In a citizen petition (now filed under docket number FDA-2014-P-0312) dated March 14, 2014, the Grocery Manufacturers Association (GMA) requests that we "issue a regulation authorizing statements such as 'natural' on foods that are or contain foods derived from biotechnology" (see Citizen Petition from the Grocery Manufacturers Association to the Food and Drug Administration ("Petition") at page 1). Specifically, GMA requests that we issue a

regulation "that it is neither false nor misleading to label a food as 'natural' or similar terms solely because the food is or contains a food derived from biotechnology" (Petition at page 3). GMA requests that FDA issue a regulation establishing that the term(s) "natural," "all natural," "100% natural," "from nature," "naturally grown," or "naturally sourced" may accompany the common or usual name of a food, or the name of a standardized food, or appear elsewhere on the label or in labeling of such foods, and that such a food shall not be deemed to be misbranded solely because the food contains a food derived from biotechnology (Petition at page 3).

Alternatively, GMA requests that we amend § 101.4 (Food; designation of ingredients.) by adding a new paragraph stating that: A food bearing a claim that its ingredient or ingredients are "natural," "all natural," "100% natural," "from nature," "naturally grown," or "naturally sourced" shall not be deemed misbranded solely because the ingredient or ingredients are derived from biotechnology (Petition at page 3, footnote 2). The GMA citizen petition also describes, in the petitioner's view, the legal and factual basis for a regulation and why rulemaking is in the public interest (see Petition at pages 5 through 15).

The GMA citizen petition follows earlier communications to FDA regarding the use of the term "natural" on the labels of food containing ingredients produced using genetic engineering. For example, three Federal district courts referred to us, for an administrative determination under 21 CFR 10.25(c), the question of whether food products containing ingredients produced using bioengineering may be labeled as "Natural," "All Natural," and/or "100% Natural." 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 (January 6, 2014)

("Courts Letter"); see also Letter from Karin F. R. Moore, Vice President and General Counsel, Grocery Manufacturers Association, to Elizabeth H. Dickinson, Esq., Chief Counsel, FDA (December 5, 2013) (mentioning the district courts' referrals to FDA and stating that FDA has authority to issue a regulation authorizing foods containing ingredients derived from biotechnology to be labeled "natural"). Although we declined to make a determination for the courts regarding whether and under what circumstances food products containing ingredients produced using genetic engineering may or may not be labeled "natural," we informed the courts that, if we were inclined to revoke, amend, or revise our policy regarding use of the term "natural," we would likely engage in a public process and work with other Federal entities, such as the U.S. Department of Agriculture (USDA) (see Courts Letter at page 2). We issued a similar response to a Federal district court, in 2010, when it asked whether high fructose corn syrup qualified as a "natural" ingredient. See Letter from Michael M. Landa, Acting Director, Center for Food Safety and Applied Nutrition, to the Honorable Jerome B. Simandle, U.S. District Court Judge, District of New Jersey (September 16, 2010).

On October 3, 2014, we received a citizen petition from Consumers Union (see FDA-2014-P-1650) requesting that we prohibit use of the term "natural" on food labels altogether. The Consumers Union citizen petition asserts that there is a "drastic" difference between FDA's current policy for use of the term "natural" and "what people think the 'natural' label should mean" (Citizen Petition from the Consumers Union to FDA ("Petition") at page 1). More specifically, Consumers Union requests that FDA issue the following interpretive rule prohibiting use of the term "natural" in food labeling: "<u>The term 'natural,' or any derivation of the term, such as 'naturally grown,' 'naturally sourced' or 'from nature,' is vague and misleading and should not be used</u>" [emphasis in the original] (see Petition at page 3).

The Consumers Union citizen petition relies on Consumer Reports National Research Center survey data to support its position that consumers are misled by the term "natural."[1] According to the petition, the survey suggests that nearly two-thirds of U.S. consumers are currently misled by use of the term "natural" on certain food labels and nearly 90 percent expect it to "mean much more than it does" (see Petition at page 2 and pages 4 through 9). For example, according to the petition, "Sixty-six percent of consumers think 'natural' processed food products mean no toxic pesticides were used, 66% think no artificial ingredients or colors were used, 65% think no chemicals were used during processing and 64% think no GMOs were used" (see Petition at page 2). Also, according to the petition, when consumers were asked what they thought the term natural should mean, "87% believe no artificial materials or chemicals should be used during processing, 86% believe no artificial ingredients or colors should be used, 86% believe no toxic pesticides should be used, and 85% believe no GMOs should be used" (see Petition at page 2).

Consumers Union asserts that it has observed a push from industry to allow the use of the term "natural" on food labels that do not represent what their survey indicates consumers believe the term natural should mean (see Petition at page 3). Consumers Union further states that "consumers demand far more from the 'natural' label, in line with what they expect from the 'organic' label" such that the term "natural" in food labeling "should be banned altogether" (see Petition at page 3).

We also have received two other citizen petitions concerning the use of the term "natural" on food labels. One citizen petition, from the Sara Lee Corp. (see FDA-2007-P-0007), asks that

[1] Consumer Reports National Research Center Survey Research Report re Citizen Petition from Consumers Union, FDA-2014-P-1650-0002. According to Consumers Union, the survey was a nationally representative phone survey of over 1000 adult U.S. residents.

we work with USDA's Food Safety Inspection Service (FSIS) to devise and adopt a unified policy, as a statement of policy, governing use of the term "natural" such that use of the term "natural" may be used to describe a food or food ingredient that does not contain any artificial flavor or flavoring, coloring ingredient (regardless of source), or any artificial or synthetic ingredient that is included within or not normally expected in the product (see Petition at page 2). Further, the Sara Lee Corp. asserts that the degree of processing necessary to produce the food or food ingredient should be considered in determining consumer expectation.

Another citizen petition, submitted by The Sugar Association (see FDA-2006-P-0206), asks that we engage in rulemaking to define the term "natural" with respect to food and beverages. The citizen petition asks for consistency across Federal Agencies with respect to such definition and requests that we define the term "natural" based on FSIS's definition in its Food Standards and Labeling Policy Book for "natural" claims for meat products and poultry products (see Petition at page 1).

The definition of "natural claims" in the FSIS's Food Standards and Labeling Policy Book, in relevant part, states that the term "natural" may be used on labeling for meat products and poultry products if the applicant for such labeling demonstrates that: (1) The product does not contain any artificial flavor or flavoring, coloring ingredient, chemical preservative (as defined in § 101.22), or any other artificial or synthetic ingredient and (2) the product and its ingredients are not more than minimally processed. The FSIS Food Standards and Labeling Policy Book further explains that minimal processing may include traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting or physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, e.g.,

grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices. The FSIS Food Standards and Labeling Policy Book also states that relatively severe processes, such as solvent extraction, acid hydrolysis, and chemical bleaching, would be considered more than minimal processing, so the use of a natural flavor or flavoring in compliance with § 101.22 that has undergone more than minimal processing would place a product in which it is used outside the scope of the FSIS guidelines. However, the FSIS Food Standards and Labeling Policy Book states that the presence of an ingredient that has been more than minimally processed would not necessarily preclude the product from being promoted as natural, and that exceptions may be granted on a case-by-case basis if it can be demonstrated that the use of such an ingredient would not significantly change the character of the product to the point that it could no longer be considered a natural product. In such cases, the natural claim is to be qualified to clearly and conspicuously identify the ingredient, e.g., "all natural or all natural ingredients except dextrose, modified food starch, etc."

The FSIS Food Standards and Labeling Policy Book also states that all products claiming to be natural or a natural food should be accompanied by a brief statement that explains what is meant by the term natural, i.e., that the product is a natural food because it contains no artificial ingredients and is only minimally processed. The statement is to appear directly beneath or beside all natural claims or, if elsewhere on the principal display panel, an asterisk should be used to tie the explanation to the claim.

Moreover, the FSIS Food Standards and Labeling Policy Book specifies that FSIS's decision to approve or deny use of a natural claim may be affected by the specific context in which the claim is made. The FSIS Food Standards and Labeling Policy Book contains an example showing that claims indicating that a product is natural food, e.g., "Natural chili" or

"chili--a natural product" would be unacceptable for a product containing beet powder, which artificially colors the finished product, but states that a claim such as "all natural ingredients" might be an acceptable claim for such a product (see Food Standards and Labeling Policy Book, FSIS, at 116, August 2005).

Both the Sara Lee Corp. and The Sugar Association citizen petitions also state that defining or establishing a policy on "natural" would provide consistency for consumers and food manufacturers.

II. Request for Comments and Information

We invite interested persons to comment on the use of the term "natural" in the labeling of human food products, including when, if ever, the use of the term is false or misleading (FDA-2014-N-1207). We are particularly interested in responses to the following questions:

- Should we define, through rulemaking, the term "natural?" Why or why not?
- Should we prohibit the term "natural" in food labeling? Why or why not?
- If we define the term "natural," what types of food should be allowed to bear the term "natural?"
- Should only raw agricultural commodities be able to bear the term? Why or why not? Section 201(r) of the FD&C Act defines the term "raw agricultural commodity" as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing."
- Should only single ingredient foods, e.g., bottled water or bagged spinach, be able to bear the term? Why or why not?

- If multi-ingredient foods should be able to bear the term, what type(s) of ingredients would disqualify the food from bearing the term? Please explain why such disqualification would be warranted.
- We are interested in any data or other information to suggest that consumers associate, confuse, or compare the term "natural" with "organic" (the USDA Agricultural Marketing Service administers the National Organic Program, which enforces laws and regulations regarding certified organic foods). We are interested in data and other information about consumers' understanding of foods labeled "natural" versus "organic." Is the term "natural" on food labels perceived by consumers the same way as "organic?" Or is "natural" perceived by consumers to be "better" (or not as good as) "organic?" Please provide consumer research or other evidence to support your comment.
- If we were to revise our policy regarding the use of the term "natural" or engage in rulemaking to establish a regulatory definition for "natural," should certain production practices used in agriculture, for example, genetic engineering, mutagenesis, hybridization, the use of pesticides, or animal husbandry practices, be a factor in defining "natural?" Why or why not?
- We are interested in any data or other information to suggest that consumers associate, confuse, or compare the term "natural" with "healthy." We have a regulation that defines the term "healthy" when used as an implied nutrient content claim with specific conditions related to the food's nutrient profile that must be met in order to use the term on the label or in labeling of a food (see § 101.65(d)). We are interested in data and other information about consumers' understanding of foods labeled "natural" versus "healthy." Is the term "natural" on food labels perceived by consumers the same way as "healthy?"

Or is "natural" perceived by consumers to be "better" (or not as good as) "healthy?" Do consumers view "natural" and "healthy" as synonymous terms? Please provide consumer research or other evidence to support your comment.

- Should manufacturing processes be considered in determining when a food can bear the term "natural?" For example, should food manufacturing processes, such as drying, salting, marinating, curing, freezing, canning, fermenting, pasteurizing, irradiating, or hydrolysis, be a factor in defining "natural?"
- Should the term "natural" only apply to "unprocessed" foods? If so, how should "unprocessed" and "processed" be defined for purposes of bearing the claim? If the term natural should include some processing methods, what should those methods be? In making determinations related to processing, should one look at the process to make a single ingredient of a food, or does one evaluate the process done to the formulated finished food product (or both)?
- The current policy regarding use of the term "natural" hinges in part on the presence or absence of synthetic ingredients. For example, under the current policy synthetic forms of Vitamin D would not be used in a food claiming to be "natural," whereas naturally sourced Vitamin D (e.g., from salmon or egg yolks) could be. Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as "natural?" Please explain your reasoning.
- 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?

- What are the public health benefits, if any, of defining the term "natural" in food labeling? Please provide supporting data and other information to support your comment.
- Should "natural" have some nutritional benefit associated with it? If so, what should be the benefit? What nutrients should be considered? What data are available to support the association between "natural" and a given nutritional benefit, and/or between "natural" and certain nutrients?
- How might we determine whether foods labeled "natural" comply with any criteria for bearing the claim?

Dated: November 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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