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BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON USE OF THE TERM “NATURAL” IN THE LABELING OF HUMAN FOOD PRODUCTS

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Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products industry. AHPA members include domestic and foreign companies doing business as growers, processors, manufacturers and marketers of herbs and herbal products, including herbal dietary supplements. AHPA serves its members by promoting the responsible commerce of products that contain herbs, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On November 12, 2015 the Food and drug Administration (FDA or the Agency) issued a Federal Register notice (the November 12 Notice) in which it reported opening of a docket to receive information and comments, which comments were solicited by the November 12 Notice on use of the term “natural” in the context of food labeling, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. The Agency explained in the November 12 Notice that it was taking this action in part because FDA has received three citizen petitions asking it to define the term “natural” for use in food labeling and one citizen petition asking for the term to be prohibited on food labels. The November 12 Notice also referenced litigation between private parties in some Federal courts over use of the term and reported that FDA is 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 is considering areas for coordination between FDA and USDA.

Numerous AHPA members market herbs and herbal products in or as foods, including conventional foods and dietary supplements, which products or contained ingredients may be labeled as “natural.” AHPA and its members therefore have an interest in appropriate regulation on the use of the term “natural” in food labeling. These comments are therefore submitted on behalf of AHPA and its members.

Comments on questions posed in the November 12 Notice

FDA posed several questions in the November 12 Notice; AHPA's responses to certain of these follow.

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

AHPA believes FDA should undertake, through rulemaking, to define the term "natural" when used on the labeling of human food products, and may consider defining additional terms, such as "100% natural" or "made with natural [named ingredient(s)]" if such additional terms would contribute to consumers' understanding of particular desirable or sought after qualities of a food. The Agency may also need to adopt regulations to establish conditions that must be met for a food to be labeled as "natural," "100% natural," "made with natural [named ingredient(s)]," and any other such "natural"-related terms as may come to be defined.

One reason FDA should define "natural" for use on food labels is simply that consumers seek such a designation on foods, with some surveys estimating that this is important to more than half of U.S. consumers.[1] Adoption of such a standard by FDA would clarify what the term means when used in labeling of foods and would establish that it always has the same meaning whenever used on food labels. The Federal Food, Drug, and Cosmetic Act has long prohibited the use in labeling of terms that are false or misleading and a primary benefit of defining the term "natural" would be to ensure that consumers are not misled by inconsistent or inaccurate use of this term in food labeling, and will be able to purchase and consume foods labeled as "natural" with a clear understanding of what the term means with regard to such issues as the agricultural practices used to grow or raise the food's ingredients and the manufacturing processes used to produce the food.

There would also be significant benefits to the regulated food industry, who are currently subject to class action lawsuits over use of the term "natural" in the vacuum of a regulatory definition of the term. An overall increase in food class action litigation has been attributed by some sources as a response to a 2009 ruling by the U.S. Court of Appeals for the Third Circuit that held that lawsuits challenging labeling of a product as "natural" are not preempted by FDA regulations.[2] Creation of a defined standard by FDA would have the

[1] The Hartman Group: Organic & Natural 2014; also: Consumer Reports® National Research Center: Natural Food Labels Survey - 2015 Nationally-Representative Phone Survey.
[2] U.S. Chamber Institute for Legal Reform. The New Lawsuit Ecosystem (October 2013).

effect of establishing a regulatory norm against which “natural” claims on food labeling can be measured, and would provide a national standard against which the allegations in such lawsuits could be measured. Moreover, a regulatory definition would require the food industry to bring their claims into alignment with this definition which should cause the number of lawsuits to be reduced substantially over time.

Should we prohibit the term “natural” in food labeling? Why or why not?

AHPA strongly opposes to any prohibition against use of the term “natural” (or related terms) when such term is accurate and not misleading. The term is presently used on the labeling of many food products and there is no basis to remove the term from any food product that is, in fact, natural. Moreover, the descriptor appears to be important to some consumers when making purchase and consumption decisions.

If we define the term “natural,” what types of food should be allowed to bear the term “natural?”

The term “natural” (and related terms) should be allowed on all types and categories of human food as well as other FDA-regulated products. The determination as to whether and when the term “natural” can be used on the label of a food should have nothing to do with the type of food but only with whether the food meets the standards for use of the term. Thus, all products sold as a foods under the Food, Drug and Cosmetic Act should be allowed to bear the defined term, including raw agricultural commodities, conventional processed foods, infant formulas, medical foods, dietary supplements, and animal foods, so long as they meet the definition that is established. AHPA furthermore believes that topical products and even drugs such as botanical drugs should be similarly allowed to use the term, as discussed elsewhere in these comments.

Should only raw agricultural commodities be able to bear the term? Why or why not?

No; AHPA is unaware of any rational basis for such a position, nor would such a position meet the needs of consumers and industry, since the vast majority of food sold in the US is not in the form of raw agricultural commodities.

Many prepared foods should meet any eventual definition of “natural” if they are made from raw agricultural commodities that meet that definition, for example if they are prepared by combining several such “natural” raw

agricultural commodities or are prepared through simple processes such as grinding or conventional cooking processes. The fact that a food has been processed by some long-established food preparation process, such as dehydrating or canning, should not disqualify it from otherwise meeting the term "natural" as it comes to be defined by FDA.[3]

In addition, such a restriction would be in direct conflict with the longstanding specific food labeling requirement established by regulation at 21 CFR 101.22 that defines the term "natural flavor or natural flavoring" to include numerous food ingredients that are not raw agricultural commodities. This rule defines the term "natural flavor or natural flavoring" to include, among other ingredients, the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, and other articles derived from plant material or described animal materials, or fermentation products thereof. None of these described articles are raw agricultural commodities, and AHPA would not support any wholesale amendment to this existing regulation.

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

No, and AHPA is unaware of any rational basis for such a position nor would such a position meet the needs of consumers and industry, since the vast majority of food sold in the US is not in the form of single-ingredient foods.

Similarly to the above comment, certainly there are conditions under which a prepared food should meet any eventual federal definition of "natural" if made from food ingredients that would also meet that definition, either by combining several such "natural" ingredients or by preparing other foods derived from these that continue to meet any eventual definition of "natural" (or related terms).[4]

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.

Depending on how FDA defines the term "natural" (or possibly "100% natural"), the inclusion of any ingredient that does not meet the eventual definition of "natural" may disqualify a multi-ingredient food from being labeled as "natural" or (or "100% natural"). On the other hand, if FDA also defines a

[3] See additional relevant comments in response to FDA's question on manufacturing processes.
[4] See additional relevant comments in response to FDA's question on manufacturing processes.

food labeling term such as "made with natural [named ingredient(s)]," a food that contains some ingredients that meet the definition of "natural" and others that do not should be able to be labeled in a manner that is clear and informative in identifying each individual ingredient that meets the "natural" definition.

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?

AHPA believes that whatever definition FDA adopts for the term "natural" for use in food labeling should prohibit use of the term on labeling of raw agricultural commodities from crops produced with genetic engineering (GE) or mutagenesis and on multi-ingredient products that include any GE- or mutagenesis-derived ingredients (except insofar as "made with natural [named ingredient(s)]" might be accurately used to describe any non-GE ingredient that otherwise qualifies as "natural" in the finished multi-ingredient product). In establishing regulations on this specific detail, FDA may find it useful to follow the lead of the USDA National Organic Program, as expressed in the following blog posting:

> "The use of genetic engineering, or genetically modified organisms (GMOs), is prohibited in organic products. This means an organic farmer can't plant GMO seeds, an organic cow can't eat GMO alfalfa or corn, and an organic soup producer can't use any GMO ingredients. To meet the USDA organic regulations, farmers and processors must show they aren't using GMOs and that they are protecting their products from contact with prohibited substances, such as GMOs, from farm to table."[5]

On the other hand, AHPA believes it is appropriate to include in the definition of "natural" those ingredients derived from crops resulting from traditional hybridization between closely related taxa and food products made from such ingredients.

With regard to the question of pesticides, AHPA notes that recent surveys indicate consumers believe "natural" labeling on food to indicate absence of chemical pesticides. However, consumers who want to purchase and consume foods that consist of or are made from ingredients that are grown

[5] http://blogs.usda.gov/2013/05/17/organic-101-can-gmos-be-used-in-organic-products; accessed May 8, 2016.

without pesticides already have a means to so by purchasing products labeled as “100% organic” or “organic” in accordance with USDA’s National Organic Program.

Furthermore, AHPA notes that conventionally-grown agricultural commodities may differ from shipment to shipment with respect to their pesticide content (i.e., some shipments may contain detectable but safe traces of legal pesticides while others may contain no detectable traces of any pesticide), and it will be impractical for food producers to change their product labeling from lot to lot based on the pesticide status of the ingredients they use.

FDA should take these and other factors into account to determine how best to address the issue of pesticides as it develops a definition for the term “natural” for use on labeling of food (and possibly other products).

In the event FDA defines the term in a manner that prohibits application of pesticides on crops that provide the raw agricultural commodities that are themselves labeled as “natural” or that provide the source materials for multi-ingredient or processed foods labeled as “natural,” AHPA believes that allowances should be made for, at a minimum, the following: (a) application of pesticides as permitted for use on crops produced organically under USDA’s National Organic Program[6]; and (b) incidental pesticide contamination resulting from airborne or water-borne drift as opposed to direct application to the crop. AHPA believes such pesticide occurrences should not disqualify an ingredient or product from being described as “natural.”

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?”

AHPA believes that in order for a food that is labeled as “natural” (or with a related term) to meet consumers’ expectations of the meaning of this term both the ingredients and the manufacturing processes must be considered. AHPA further believes a “natural” processed food must necessarily be derived only from “natural” ingredients and must be processed in a manner that retains the natural quality of the starting ingredients.

While attention to manufacturing processes may complicate the regulatory process of defining the term “natural” for use on food labeling, and in particular

[6] 7 CFR Part 205: National Organic Program.

for use on labeling of processed foods, a rational line can be drawn between processes that can be acknowledged as retaining the “natural” quality of a processed food’s ingredients in a finished food product and processes that would not do so.

Specifically, AHPA believes any food manufacturing process that is a traditional food preparation process, as described below, should be recognized as maintaining the “natural” quality of the ingredients used to make a multi-ingredient or processed food, such that any processed food derived from ingredients that meet the standard for “natural” should itself be allowed to be labeled as “natural.”

AHPA suggests that food processing that involves some or all of the following steps (not necessarily in any particular order) should be identified as traditional food preparation processes for this purpose:

- Obtaining suitable ingredients that meet the “natural” standard.
- Drying, lyophilization, or other removal of moisture.
- Reducing the size as necessary, e.g., by milling, chopping, cutting, or grinding.
- Fermentation or other microbiological processes alone or in combination with other food ingredients, using wild inoculations or specific, traditionally cultivated strains of microorganisms.
- Heating, cooking, baking, frying, pressure cooking, roasting, grilling, steaming, smoking, cooling, refrigerating, freezing, or otherwise applying wet or dry heat or cold in any manner and in any combination with other food ingredients, at suitable conditions of temperature, pressure, and agitation.
- Extraction by soaking, steeping, infusing, macerating, percolating, or steaming in or with water; wine, liquor, ethanol, or a hydroethanolic mixture; vinegar; glycerin; honey; a food oil; or other suitable liquid which is itself a food, at suitable conditions of temperature, pressure, and agitation.
- Straining, filtering, pressing, or squeezing.
- Peeling.
- Coating.
- Curing without the use of purified chemical additives other than salt.
- Distilling or rectifying.
- Evaporating.

- Mixing, combining, or emulsifying with other food ingredients by stirring, shaking, or other means.

On the other hand, a processed food would not be “natural” if it is concentrated or chemically altered in a manner other than through traditional food preparation methods, as described above; if the food processing includes non-traditional process steps, or uses non-traditional extraction solvents or fermentation inoculates; if non-traditional process steps intended to concentrate a particular constituent or class of constituents are used; or if process steps are used that otherwise alter the chemical or microbiological composition of the food or ingredient in a manner inconsistent with traditional preparations of the food.

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)?

No. AHPA has presented comments above relevant to this question. These comments apply to both the processes used to make a single ingredient and those use to make a formulated food product.

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.

AHPA does not believe a synthetic ingredient can be labeled as “natural” under any common understanding of the meaning of the word “natural” and AHPA further believes any regulation on the use of the term established by FDA should prohibit synthetic ingredients and multi-ingredient food products that contain synthetic ingredients from being labeled as “natural” (except insofar as “made with natural [named ingredient(s)]” might be accurately used to describe any non-synthetic ingredient that otherwise qualifies as “natural” in the finished multi-ingredient product).

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 AHPA's view, the best way to ensure that consumers have a consistent and accurate understanding of the term "natural" in food labeling to ensure it is not misleading is for FDA to establish, through rulemaking, a definition of the term "natural" that is reasonably consistent with consumers' understanding of the term, as shown through market research; to consider defining additional terms, such as "100% natural" or "made with natural [named ingredient(s)]" since such additional terms will contribute to consumers' understanding of particular desirable or sought after qualities of a food; to adopt regulations to establish conditions that must be met for a food to be labeled as "natural," "100% natural," "made with natural [named ingredient(s)]," and any other such natural-related terms as may come to be defined; and to enforce the resultant regulations after a reasonable compliance period.

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.

As stated elsewhere in these comments, AHPA supports FDA's establishment of a definition of "natural" for use in food labeling to provide this information to the majority of U.S. consumers who seek such a designation for foods and to ensure that consumers are not misled by the use of this term in food labeling, consistent with the longstanding statutory prohibition against the use in labeling of terms that are false or misleading.

AHPA believes there may be a public health benefit to defining the term "natural" for use in food labeling (and in other FDA-regulated goods), insofar as this rulemaking should be assumed to have the effect of providing consumers with additional accurate information that may affect their food choices, and further assuming that a more informed consumer is generally best able to make better health related decisions.

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?

AHPA does not believe that "natural" labeling of food products should be required to have some nutritional benefit associated with it. AHPA believes the primary benefits for both consumers and industry of having FDA establish regulations on use of the term "natural" (and possibly related terms) are to provide this information to the majority of U.S. consumers who seek such a designation on foods, to ensure that consumers are not misled by the use of this term in food labeling, and to provide industry with a level playing field and relief from frivolous lawsuits.

How might we determine whether foods labeled "natural" comply with any criteria for bearing the claim?

AHPA believes FDA has significant authority to enforce all food labeling rules and that this same authority should be applied to determine whether foods labeled "natural" comply with whatever criteria comes to be established through rulemaking for bearing this claim.

In order to ascertain compliance with criteria for bearing any "natural" claim, AHPA believes it will be necessary for manufacturers to maintain documentation of the ingredients and manufacturing processes used to produce the product bearing the claim, and to make such documentation available for FDA review.[7] This approach is not novel; for example, FDA uses a similar approach to determine compliance with soy protein labeling claims,[8] and FDA has proposed similar mechanisms with respect to other label claims.[9]

[7] Where a packager that is not the product manufacturer applies labeling bearing a "natural" claim, AHPA believes the packager should be required to obtain from the product manufacturer a written guarantee (on a one-time basis rather than annually) that the product to be packaged meets the requirements for the claim.
[8] 21 CFR 101.82: Health claims: Soy protein and risk of coronary heart disease (CHD); specifically 21 CFR 101.82 (c)(2)(ii)(B).
[9] 79 FR 11880 at 11956: 21 CFR Part 101 Food Labeling: Revision of the Nutrition and Supplement Facts Labels; Proposed Rule, March 3, 2014.

The term "natural" should also be defined for use on labeling of other FDA-regulated products

Just as AHPA believes FDA should undertake to define the term "natural" when used on the labeling of human food products, AHPA also believes the Agency should extend the rulemaking to similarly define the term "natural" (and possibly additional terms, such as "100% natural" or "made with natural [named ingredient(s)]") for other FDA-regulated goods, including at a minimum animal foods, cosmetics, and botanical drugs.

From the perspectives of both consumers and regulated industries, the issues are the same for these other products as for human foods. Consumers need the meaning of the term "natural" to be clearly defined and consistently used in labeling on any FDA-regulated products where the term may appear, and the term should have the same meaning for all regulated goods encountered in the marketplace. In addition, companies that sell products that may be able to be labeled as "natural" need clear guidance on their use of the term, irrespective of the specific product category.

The one class of food ingredients for which there is a current regulatory definition of "natural" is for the term "natural flavor or natural flavoring." AHPA notes this term is defined in two separate locations in Title 21 of the Code of Federal Regulations, specifically in 21 CFR 101.22 (a)(3) as the term affects "Specific Food Labeling Requirements" for human food labeling; and in 21 CFR 501.22 (a)(3) as the term affects "Specific Animal Food Labeling Requirements" for animal food labeling. Thus, there is a precedent under current labeling regulations to apply a "natural" definition to both human and animal food labeling; AHPA believes this precedent should be applied, and in fact extended to also include cosmetic products and botanical drugs, with regard to rulemaking for more general "natural" labeling.

AHPA supports FDA's cooperation with other agencies

In the November 12 Notice, FDA stated it is working with the 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 is considering areas for coordination between FDA and USDA.

AHPA supports the described cooperation with USDA and believes one goal of such cooperation should be to ensure that all definitions for the term "natural" adopted by any federal regulatory agency for use of this term on any food products – whether regulated by FDA or USDA – are sufficiently similar to avoid consumer confusion.

In addition and as mentioned elsewhere in these comments, AHPA also suggests FDA's cooperation with USDA's National Organic Program to the degree that agency's regulation of the terms "organic," "100% organic," and "made with organic [named ingredient(s)]" may be relevant to FDA's rulemaking on defining the term "natural" (and possibly related terms).

The current definition of "natural flavor or natural flavoring" should be retained

AHPA notes the terms "natural flavor or natural flavoring" has long been defined under regulation, for both human and animal foods, as follows:

> The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter [i.e., 21 CFR], and the substances listed in 172.510 of this chapter.[10]

AHPA believes this definition should be retained for the term "natural flavor or natural flavoring" in labeling of human and animal foods, as consumers currently consider these to be "natural" food ingredients. AHPA further believes, however, that if FDA accepts AHPA's position that food articles derived from crops produced through genetic engineering or mutagenesis should not be labeled as "natural," then flavors or flavorings derived from such crops should also not be labeled as "natural."

Summary and conclusions

In these comments AHPA has answered most of the questions posed by FDA in its November 12, 2015 Notice. In so doing, AHPA has expressed its belief that the Agency should establish, through rulemaking, a regulatory definition for the term "natural" (and possibly other terms, such as "100% natural" and "made with natural [named ingredient(s)]") when used on the labeling of human food products, and in addition has recommended such a definition should also be established for labeling

[10] 21 CFR 101.22 (a)(3): Foods; labeling of spices, flavorings, colorings and chemical preservatives; and 21 CFR 501.22 (a)(3): Animal foods; labeling of spices, flavorings, colorings, and chemical preservatives.

of other products regulated by FDA such as animal foods, cosmetics, and botanical drugs. AHPA has also suggested that the term (or terms) be allowed on labeling not only on raw agricultural products but also on multi-ingredient and processed foods, and has shared ideas about how the term “natural” should be defined and how FDA should enforce any resulting rule. AHPA has also expressed support for FDA’s cooperation with USDA to ensure consistent use of “natural” labeling of all foods, irrespective of agency jurisdiction, and has also recommended that current regulatory definitions of “natural flavor and natural flavoring” be retained.

AHPA greatly appreciates the opportunity to present comments on this matter. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

Respectfully submitted,

Michael McGuffin
President, American Herbal Products Association
8630 Fenton Street, Suite 918
Silver Spring, MD 20910
(301) 588-1171 x201
mmcguffin@ahpa.org

Anthony L. Young
General Counsel, American Herbal Products Association
Kleinfeld, Kaplan and Becker, LLP
1850 M Street, N.W., Suite 900
Washington, DC 20036
(202) 223-5120
ayoung@kkblaw.com