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Via Electronic Transmission

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

Re: Food and Drug Administration Docket Number FDA-2014-N-1207: Request for Comments and Information on the Use of the term "Natural" in the Labeling of Human Food Products, 80 Fed. Reg. 218 (November 12, 2015)

To Whom It May Concern:

On behalf of the International Association of Color Manufacturers (IACM), we appreciate the opportunity to submit comments in response to the Food and Drug Administration's (FDA) request for comments and information on the use of the term ''natural'' in the labeling of human food products (80 *Fed. Reg.* 69905 (Nov. 12, 2015)).

I. Introduction

IACM is the trade association that represents the global color industry, comprised of manufacturers and end-users of coloring substances that are used in foods, including certified and exempt from certification colors. IACM members create and use colors for a wide variety of food and beverage products.

II. Executive Summary

FDA has established 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. The agency is taking this action in part because FDA received three citizen petitions asking that FDA define the term ''natural'' for use in food labeling and one citizen petition asking that the agency prohibit the term ''natural'' on food labels. Additionally 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.'' 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 are considering areas for coordination between FDA and USDA.

FDA has a longstanding policy for the use of the term ''natural'' on the labels of human food. The agency previously considered establishing a definition for the term ''natural'' when used in food labeling. In the preamble of a proposed rule to implement the Nutrition Labeling and Education Act of 1990 (56 *Fed. Reg.* 60421 (November 27, 1991), FDA said that the agency has not attempted to restrict use of the term ''natural'' except for added color, synthetic substances, and synthetic flavors under § 101.22 (21 CFR 101.22) (56 *Fed. Reg.* 60421 at 60466). Further, FDA stated that the agency has 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 *Fed. Reg*. 60421 at 60466).

FDA has 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, the agency said, back in 1991, that FDA was considering establishing a definition for this term (56 *Fed. Reg.* 60421 at 60466). FDA believed that defining the term ''natural'' could remove some ambiguity surrounding use of the term that results in misleading claims (56 *Fed. Reg.* 60421 at 60466). The agency invited comments on several questions, including whether FDA should establish a definition for ''natural," or whether it should prohibit ''natural'' claims entirely on the grounds that they are false or misleading (56 *Fed. Reg.* 60421 at 60467). In the preamble to the subsequent final rule, the agency noted that FDA 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). The agency stated that at that time FDA would not be engaging in rulemaking to define ''natural,'' but that the agency would maintain its policy not to restrict the use of the term ''natural'' except for added color, synthetic substances, and synthetic flavors. FDA further stated that the agency would maintain its 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 *Fed. Reg.* 2302 at 2407).

IACM believes that American consumer perception and interest in "natural" foods and naturally derived food ingredients, including color additives, has evolved, and due to consumer confusion associated with the lack of a definition for the term "natural color," a term that is widely used by consumers both in the US and globally to refer to color additives derived from natural sources, FDA should define the term "natural color" and allow that term to be used in product labeling when added color meets that definition and/or should FDA define the term "natural," permit "natural color" to be added to foods labeled as "natural." IACM would also posit that FDA could create a definition or policy that would allow for defined ingredients to be used when a product is advertised as being "made with natural ingredients" and that colors meeting the proposed definition of "natural color" be allowed to be used in such products.

III. FDA Should Establish a Definition for the Term "Natural Color"

Color additives are used to reinforce colors in food and to ensure uniformity of food from season to season and batch to batch. Until the mid-1800s, the only external sources of colorings added to foods were natural, derived from animals, vegetables, and minerals, such as saffron and carrots, which are still safely used to color food today.

The members of IACM have acknowledged and abided by FDA's current policy interpreting the use of the term "natural" on food labels as it applies to added color for many years. However, we respectfully note that since the policy was first articulated by FDA, the food color industry has undergone a shift and now many more colors and colored products are

produced containing ingredients derived from natural sources, in large part due to consumer demand. We would also note that applied to a substance, artificial means that the molecular structure of such a substance has not been identified in nature and in biological terms it means that the substance is not known to the human physiology.

FDA's current policy was established during a time when IACM members were just beginning to investigate the range of applications for naturally derived color additives and before consumer demand began to dictate the dramatic increase in natural and organic food products. However, these consumers also often desire natural food from the center of the grocery store to complement the fresh produce and meat products that they purchase. While the portfolio of approved colors derived from natural sources has only increased minimally in the last 25 years, the use of the available palate of colors has increased dramatically. Certified colors still remain the most popular type of food coloring in the US due to their brightness, uniformity, characterization, and cost. However, consumer interest in naturally derived color additives has increased the use of colors from natural sources, and IACM members are innovating to meet the needs of their customers and the savvy shopper.

Food colors are of great benefit to both consumers and processors. First, food color is an important property of foods that adds to a person's enjoyment of eating. By defining "natural color" and allowing food products to be labeled as containing "natural color" and/or allowing "natural color" to be added to foods bearing a "natural" label, consumers seeking natural food options will have more variety of natural food choices. Consumers already expect certain foods to contain added color and appreciate the benefits of added color including: offsetting color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; correcting natural variations in color; enhancing colors that occur naturally but at levels weaker than those usually associated with a given food; providing a colorful identity to foods that would otherwise be virtually colorless; enhancing the flavor expectations of food; and most importantly to provide an appealing variety of wholesome and nutritious foods that meet consumer expectations and demands. Moreover, the addition of color also provides assurance of a uniform and homogeneous dosage of the color in the target food as well as convenience in handling during food production.

Many consumers selecting natural foods already select foods with added color derived from natural sources. The current color additive labeling regulations make it easy for consumers to identify both when color is added and what specific color is added to the food. By defining "natural color" and permitting the addition of "natural color" to foods labeled as "natural" or "with natural ingredients," consumers will still be able to readily identify when foods contain added color, but will have more information about the natural source of the color added to that food so that the consumer can make a buying decision based on their individual preferences.

IACM does agree with the agency's hypothesis that defining the term "natural" could remove the ambiguity surrounding use of the term as well as help to provide a common consumer understanding. Additionally, IACM's members manufacture color additives and food products for use globally, and the term "natural color" is used in regulations and in common practice in many parts of the world to apply to those colors referred to as exempt from certification in the US. IACM members must compete with companies based outside of the US who do not always understand or abide by FDA's current policy with respect to the labeling of colors, and as FDA is aware, this can result in colors marketed in the US that are mislabeled.

Because of all the reasons stated above, IACM feels strongly that the time is now ripe for FDA to define the term "natural color." The legal specifications for the food colors usually contain a manufacturing process description as part of the specification. The specification for a

given food color may contain descriptions of more than one manufacturing process. As some legal specifications of food colors cover more than one manufacturing process, colors within a given regulation may be split when categorized for the purpose of "natural color" claims. IACM's proposed definition of "natural color" is:

> *The term natural color means a color additive that is derived from plant, animal, mineral or microbiological sources through appropriate processes and whose significant technical function in food is coloring. Appropriate processes may include but are not limited to grinding, cutting, maceration, solvent extraction, microbiological fermentation processes, heating, roasting, enzymolysis, hydrolysis, cooling and freezing, drying, filtration, distillation, rectification, absorption/adsorption, chromatography, ion-exchange, electrophoresis, ultrasonic treatment, centrifugation, (reverse) osmosis, crystallization, precipitation, lyophilization, and enzymatic processes.*

IACM would support the development of a list of colors meeting this definition and would be happy to provide more detail and thought around the criteria and list of appropriate colors upon request and in consultation with the agency.

IV. FDA could allow for use of "made with natural ingredients" either through regulation or policy

In addition to defining and permitting the use of the term "natural" for the labeling of foods, IACM would also support FDA providing guidance or establishing regulation as to when a food may be accurately labeled to be "made with natural ingredients," and strongly recommends that if FDA establishes such a labeling scheme, that the agency permits "natural colors" to be added to such foods. IACM believes that allowing for a product that meets the criteria defined by FDA to be labeled as "made with natural ingredients" would provide consistency for consumers and food manufacturers as requested by the petitioners Sara Lee and the Sugar Association.

There is precedent for naturally derived color to be considered a lawful ingredient in a product labeled as "made with natural ingredients." For example, the Canadian Food Inspection Agency maintains a Guide to Food Labelling and Advertising[1], which indicates that "some food additives, vitamins and mineral nutrients may be derived from natural sources. Some of these additives may be regarded as natural ingredients, in which case the acceptable claim would be that this food contains 'natural ingredients.' The processes used to produce the food additive should not significantly alter its original, chemical, or biological state. Note that while the ingredient can be described as 'natural,' the food itself cannot, since it contains an added component." If FDA were to follow this approach, the agency could define what sources of ingredients are allowed to be considered as included in a product to be labeled "made with natural ingredients," as opposed to defining what products themselves were to be included as "natural," which would provide clarity to the consumer and to the food industry. Through this approach, IACM would again urge FDA to consider what sources of color could be considered natural and able to be included in such a claim, regardless of whether FDA choose to define the term "natural color" in regulation.

Another reason for taking this approach is a recognition by FDA that there are many food ingredients that, in addition to their color additive function, have another permitted food function. This is significant because, for many of these dual functioning, naturally derived food

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[1] http://www.inspection.gc.ca/food/labelling/food-labelling-for-industry/method-of-production-claims/eng/1389379565794/1389380926083?chap=2

ingredients, if added to food strictly for its non-color function, the finished food, in accordance with FDA's current policy on "natural" labeling, may be labeled as "natural." For example, lycopene can be used as an antioxidant but is also regulated for use as an exempt for certification color additive. There are other ingredients that have GRAS status but have also been the subject of a color additive petition and granted status as an exempt from certification color additive, since GRAS status does not apply to color use. An example of such an ingredient is beta-carotene that is GRAS for use as a nutrient supplement (21 CFR 184.1245) but is also approved as an exempt from certification color that can be derived from natural sources (21 CFR 73.95).

IACM would argue that because color additives are closely regulated and subject to pre-market review and approval by FDA, there are no concerns as to whether naturally derived color additives are safe. However, the current FDA policy, which prohibits food products from bearing a "natural" label where it includes added color, no matter the source, creates an inconsistency between how foods containing, for example, naturally derived lycopene for its antioxidant effect versus color may be labeled. This inconsistency should be rectified in equity by FDA since both ingredients may be derived from the same or similar source. IACM requests FDA to consider an ingredient's source when developing a definition of "natural" or a policy for the claim "made with natural ingredients" for labeling purposes as opposed to focusing simply the ingredient's function in the product. The same consumer who is seeking a natural ingredient such as lycopene for its antioxidant qualities may be pleased to know that the product's red color could be a result of the same naturally derived ingredient. Furthermore, the ingredients permitted by FDA to color foods fall into different categories that the consumer is hardly aware of (certified and exempt from certification), and that are meaningless from a labeling perspective and unique to the US regulatory environment.

The European Commission's Standing Committee on the Food Chain and Animal Health has adopted guidance[2] to specify that coloring ingredients can be considered coloring foods rather than coloring additives if they are derived from fruits, vegetables, herbs or other foods that have been usually consumed in the EU since before 2007. The guidance also says they should be minimally processed and should retain the characteristics of the source material, among other specifications. While labeling is not covered in the guidance, the expectation by IACM members doing business in the European market is that the coloring food will continue to be labeled, but it would not require the use of an E number, which could be considered the equivalent to having to be labeled as "artificial" in the US. A list of accepted colors is currently in development, but it is expected to include naturally derived colors such as saffron and spirulina extract, which are approved for use as exempt from certification colors in the US. IACM shared this guidance with the agency when it was first released, and while we do not anticipate that FDA will necessarily adopt a similar approach, we would argue that allowing for colors that meet the definition of coloring food in the EU and allowing for use of the term "natural color" or certain colors to be included in a claim of "made with natural ingredients" would bring the US closer to the EU and other global markets and ease the burden on companies having to label products differently in different markets. This would also offer clarity to the consumer, as we would argue that the average consumer can understand that commercial color preparations are necessary to assure a uniform and homogeneous dosage of the color in the food and to provide convenience in handling during food production, and that certain naturally derived colors could and should be allowed to be included in a product making a claim of "made with natural ingredients."

[2] http://ec.europa.eu/food/safety/docs/fs_food-improvement-agents_guidance_additive-eu-rules.pdf

V. IACM Responses to Specific FDA Questions

IACM is pleased to provide comments in response to FDA's request for information which support the establishment of a regulatory definition for the term "natural color" and allow the term to be used on the labels of food products that contain ingredients meeting this definition.

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

Yes, IACM 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 the 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. Additionally, IACM recommends that FDA define the term "natural" as it applies to food colors, as there is a subset of naturally derived food colors that are widely considered as "natural" in international markets, and the lack of a recognition of this term in the US creates confusion and barriers to trade. Consumers globally, including in the US, often consider these colors as natural already and providing a clear definition for the term would help to alleviate consumer confusion.

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, consumer nonetheless continue to look for natural food options. If properly defined, the term can provide the consumer with information about the source of ingredients in a product.

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

IACM requests that FDA define the term "natural" for use in food labeling such that any food which includes "natural color" will qualify for "natural" labeling.

IACM recommends that FDA define natural color as:

The term natural color means a color additive that is derived from plant, animal, mineral or microbiological sources through appropriate processes and whose significant technical function in food is coloring. Appropriate processes may include but are not limited to grinding, cutting, maceration, solvent extraction, microbiological fermentation processes, heating, roasting, enzymolysis, hydrolysis, cooling and freezing, drying, filtration, distillation, rectification, absorption/adsorption, chromatography, ion-exchange, electrophoresis, ultrasonic treatment, centrifugation, (reverse) osmosis, crystallization, precipitation, lyophilization, and enzymatic processes.

This definition would be in line with how manufacturers consider and label products containing natural color in the EU. IACM would recommend that only products with colors meeting this definition would be allowed to be labeled as containing natural color.

- **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.

In addition to single ingredient foods, consumers appear to search for and purchase multi-ingredient packaged foods labeled as "natural." As such, FDA should consider a more expansive definition of "natural" to include such foods. IACM supports the term "natural" on foods including those food that contain "natural color." For purposes of products containing added color, we would again suggest that only multi-ingredient foods containing those colors that meet the proposed definition of natural color be allowed to use the term "natural color" on the labels of their products.

- **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)?**

IACM suggests that appropriate processes should be a consideration in determining when a food could be labeled as containing "natural color" and that the term "natural" could apply to processed foods. Appropriate processes may include but are not limited to grinding, cutting, maceration, solvent extraction, microbiological fermentation processes, heating, roasting, enzymolysis, hydrolysis, cooling and freezing, drying, filtration, distillation, rectification, absorption/adsorption, chromatography, ion-exchange, electrophoresis, ultrasonic treatment, centrifugation, (reverse) osmosis, crystallization, precipitation, lyophilization, and enzymatic processes.

- **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.**

IACM agrees that the manner in which an ingredient is produced or sourced should affect whether a food containing an ingredient may be labeled as "natural." In fact, IACM encourages FDA to define natural ingredients by source, not by function. Traditionally, according to FDA policy, any color added to a product is considered artificial. However, there are dual use ingredients, such as turmeric, that when used as a spice, are able to be used in a finished product that is considered as natural under current FDA policy, but when added as a color additive, the food product cannot be labeled as natural. Consumers have an expectation that certain foods will be certain colors due to the traditional practice of adding color to food for a myriad of reasons, including to offset color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; correct natural variations in color; enhance colors that occur naturally; provide an identity to otherwise colorless foods; and to enhance the flavor expectations

of food. While colors from a variety of sources are able to be used to achieve many of these effects, consumers who prefer “natural” food products should be able to experience food colored with those colors that are naturally sourced.

- **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?**

IACM suggests that consumers would have a consistent and accurate understanding of the term “natural” in food labeling if FDA were to provide clear definitions of what qualifies as natural, and if that definition were consistent with how foods including natural color are defined in other parts of the world.

- **How might we determine whether foods labeled ‘‘natural’’ comply with any criteria for bearing the claim?**

IACM would request that FDA utilize the definition offered by IACM for “natural color” as criteria that would assist both FDA and the regulated industry in determining whether color added to food would qualify as “natural color” and thereby be allowed in foods labeled as “natural.” Alternatively, FDA could offer guidance through regulation or policy that certain ingredients, including naturally derived color, would be allowed in a product with the labeling claims “made with natural ingredients.”

VI. Conclusion

IACM appreciates the opportunity to comment and urges your consideration of these important matters as you consider the use of the term “natural” in the labeling of human food products.

Sincerely,

Sarah A. Codrea

Sarah A. Codrea
Executive Director