



Andrew C. Briscoe III
President and CEO
The Sugar Association, Inc.
1101 15th Street, NW
Suite 600
Washington, DC 20005

Re: Docket No. 2006P-0094/CP 1

Dear Mr. Briscoe:

This letter is in response to your citizen petition, dated February 28, 2006, requesting the Food and Drug Administration to initiate rulemaking to establish regulations that define the word "natural" before a "natural" claim can be made on foods and beverages regulated by FDA.

In accordance with 21 CFR 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt. Because of competing agency priorities and the limited availability of resources, we have not been able to respond to your petition. We hope to be able to complete the review of your petition and respond to your request in the near future.

Should you have additional questions, do not hesitate to contact us.

Sincerely yours,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2006P-0094

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFS-820	Sara Hockmuth	7/1/06	HFS-800	Schneeman	8/3/06			
HFS-820	Jane	8/2/06						
HFS-800	Barbara	8/2/06						
HFS-800	Barbara	8/3/06						

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**AUG 22 2006**

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February 28, 2006

Docket Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: Citizen Petition re Definition of the term "Natural" for making claims on foods and beverages regulated by the Food and Drug Administration

Dear Sirs and Madams:

The Sugar Association submits this petition pursuant to 21 C.F.R. § 10.30.

Action Requested

The Sugar Association (Association) requests the Commissioner of Food and Drugs (FDA) undertake rulemaking to establish specific rules and regulations governing the definition of "natural" before a "natural" claim can be made on foods and beverages regulated by the FDA.

The Association requests that FDA maintain consistency across Federal agencies and define the term "natural" based on the definition provided in the United States Department of Agriculture (USDA) *Food Standards and Labeling Policy Book*. USDA requires the following concise definition be met before a "natural" claim is permitted on meat and poultry products.¹

NATURAL CLAIMS:

The term —"natural" may be used on labeling for meat products and poultry products, provided the applicant for such labeling demonstrates that:

- (1) The product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative (as defined in 21 CFR 101.22), or any other artificial or synthetic ingredient; and (2) the product and its ingredients are not more than minimally processed. Minimal processing may include: (a) those 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 (b) those physical processes

¹ USDA Food Standards and Labeling Policy Book, August 2005. Accessed Dec. 14, 2005 at http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf.

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THE SUGAR ASSOCIATION, INC.

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2006P.0094

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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.

(2) Relatively severe processes, e.g., solvent extraction, acid hydrolysis, and chemical bleaching would clearly be considered more than minimal processing. Thus, the use of a natural flavor or flavoring in compliance with 21 CFR 101.22 which has undergone more than minimal processing would place a product in which it is used outside the scope of these guidelines. However, the presence of an ingredient which has been more than minimally processed would not necessarily preclude the product from being promoted as natural. Exceptions of this type 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 must be qualified to clearly and conspicuously identify the ingredient, e.g., "all natural or all natural ingredients except dextrose, modified food starch, etc."

All products claiming to be natural or a natural food should be accompanied by a brief statement which 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. This statement should 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.

The decision to approve or deny the use of a natural claim may be affected by the specific context in which the claim is made. For example, 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. However, "all natural ingredients" might be an acceptable claim for such a product.

Note: Sugar, sodium lactate (from a corn source), natural flavorings from oleoresins or extractives are acceptable for —all natural claims.

This entry cancels Policy Memo 055 dated November 22, 1982.

See: 7 CFR NOP Final Report, Part 205.601 through 205.606 for acceptable ingredients allowed for all natural claims.

Labeling that is false or misleading in any particular is prohibited under the misbranding provision of the Food Drug and Cosmetic Act (FDCA). The Association requests regulations mandate that foods and beverages represented as "natural" that do not meet the above criterion be deemed misbranded under section 403(a) of the FDCA.

Background

FDA has not undertaken rulemaking to provide food and beverage manufacturers with concise regulations for making a "natural" claim on food and beverage products regulated by the Agency. Food and beverage manufacturers are therefore permitted to interpret general principles established by FDA prior to 1991. In its 1991 Notice of Proposed Rulemaking (NPR) for the Nutrition Labeling and Education Act (NLEA), FDA solicited comments on the use of the term natural. At that time FDA acknowledged "The meaning and use of the term natural on the label are of considerable interest to consumers and industry."²

In the 1993 NLEA final rule, FDA stated it "believed that if the term 'natural' were adequately defined, the ambiguity in the use of this term, which has resulted in misleading claims, could be abated."³ Citing resource limitations and other Agency priorities, FDA did not undertake rulemaking in 1993 but instead maintained its previous informal policy of general principles.⁴

The current policy has engendered a great deal of ambiguity. In its 1991 NPR, FDA acknowledged that use of the informal definition for "natural" as applied to foods absent of artificial or synthetic ingredients, has degraded the meaning of the term by its inappropriate use in the marketplace.⁵ In the 12 years since FDA last solicited comments on establishing rules for the use of "natural" claims in labeling, consumer interest in natural products has risen considerably. Therefore, FDA rulemaking on this important consumer consideration for purchasing foods and beverages is not only timely but is necessary to preserve consumer trust as well as safeguard the interests of companies that market natural products.

Consumer Interest in Natural Products

The steady growth of consumer interest in natural and organic products is well documented with "all-natural" reported to be the most frequent "positive" new product category.^{6,7,8} In 2004, the National Marketing Institute reported that 63% of consumers

² Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms, 56 Fed. Reg. 60,466 - 60,467 (November 27, 1991).

³ Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms, 58 Fed. Reg. 2407 (January 6, 1993).

⁴ "The Agency will maintain its current policy not to restrict the use of the term "natural" except for added color, synthetic substances, and flavors as provided in §101.22. Additionally, the agency will maintain its policy regarding the use of the term "natural" as meaning nothing artificial or synthetic (including color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlined in §101.22." 58 Fed. Reg. 2407 (January 6, 1993).

⁵ *Id.* 56 Fed. Reg. 60,466 - 60,467.

⁶ Food Marketing Institute, *Natural and Organic Foods*, FMI.org, accessed Dec. 14, 2005 at http://www.fmi.org/media/bg/natural_organic_foods.pdf.

⁷ E A Sloan, "Natural Foods Marketing Direction," *Food Technology* 57, no.5 (2003): 14.

⁸ E A Sloan, "2005 Annual Meeting Expo Review New Product Trends," *Food Technology* 59 no. 9 (2005): S36-44.

have a preference for natural foods and beverages.⁹ This consumer trend is also evident by the growing number of thriving businesses catering to consumers wishing to purchase natural food products as food sales in natural product stores reached a reported \$11.4 billion in 2003.¹⁰

Furthermore, according to the Iowa State University Agricultural Marketing Resource Center, "the combination natural/organic food category has grown significantly since 1990, increasing four-fold in the decade after and averaging 14 percent annual growth (compared to historic growth rate of 4 percent in the overall food industry)."¹¹

While consumer interest in natural products continues to grow, there have also been dramatic changes in the US food supply over the past 12 years. FDA currently lists over 3000 approved additives in its report *"Everything" Added to Food in the United States* (EAFUS). By contrast, the European Union (EU) identifies 311 approved food additives¹² and the Food Standards Agency of Australia and New Zealand reports only 299.¹³ These comparisons are not made to assert that the expansive number of food additives, ingredients and ingredient blends permitted in the US degrade the food supply or to question the safety of an artificial additive. The Association acknowledges the many benefits food technology has contributed to assuring the safety of the US food supply.

Further, the Association acknowledges that the EAFUS list includes processing aids and other categories not identified as food additives in the EU. However, with today's escalating reformulation of long-established food products, resulting in dramatic changes in the US food supply, FDA should establish regulations that mandate strict industry guidelines that ensure that "natural" claims do not mislead the growing number of consumers who value and wish to purchase natural products. Such rulemaking would help eliminate consumer confusion and minimize misleading claims.

Further, for those companies deciding to provide natural products for this growing number of consumers, a precise definition of the term "natural" would provide the very continuity such claims require and would help eliminate misleading competitive practices.

Minimally Processed

The Association contends that the proposed combination of the two criteria put forth in this petition for allowing a "natural" claim – 1) a food that does not contain anything artificial or synthetic and 2) a food or food ingredient is not more than

⁹ E A Sloan, "Gourmet & Specialty Food Trends," *Food Technology* 58 no. 7 (2004): 26-38.

¹⁰ *Id.* 9

¹¹ J. Norwood, "Natural Products," Agricultural Marketing Resource Center, Iowa State University, January 2004. Accessed Dec. 14, 2005 at <http://www.agmrc.org/NR/rdonlyres/61DAD87B-9BE8-41C0-8161-0391DD070917/0/naturalfoodsnorwood.pdf>.

¹² List of Current European Union-approved additives, Food Standards Agency. Accessed October 12, 2005 at <http://www.food.gov.uk/safereating/additivesbranch/enumberlist?v>

¹³ Food Additives, Food Standards of Australia and New Zealand. Accessed Dec 14, 2005 at <http://www.foodstandards.gov.au/mediareleasespublications/publications/shoppersguide/foodadditivesalphaup1679.cfm>

minimally processed – achieves a level of specificity that will negate much of the current ambiguity associated with a "natural" claim.

In the 1991 NPR, FDA asked for comments on the meaning of minimally processed.¹⁴ Further, FDA has expressed concerns about the potential for ambiguity in defining the term "minimally" processed. To this matter, the Association cites the USDA minimally processed criterion "those physical processes which do not fundamentally alter the raw product" for evaluating whether or not a product or ingredient is minimally processed, as the guidance sought by FDA.

Similarly, the Canadian Food Inspection Agency (CFIA) has deemed that only foods or food ingredients whose processing has not significantly altered the original physical, chemical or biological state can be described as "natural."¹⁵ Therefore, according to the USDA and CFIA minimally processed standards, preservation of the molecular structure inherent in the raw material is an obligatory requirement before a food or beverage ingredient can be labeled as "natural."

A minimally processed food ingredient can be claimed to be "natural" only when processing does not affect the natural character of the food or its molecular structure is identical to that present in the raw material from which it was physically separated. Flour, nonhydrogenated oils and sugar from sugar cane or sugar beets are three examples of "natural" food ingredients.

Processes such as hydrolysis or enzymolysis where the raw material is fundamentally altered to the extent that these processes manipulate the molecules of one substance to create another would preclude a "natural" claim. For example, with common starch-based sweeteners, the final products are absent in the host plants from which they are manufactured. The original chemical state of the starch-based sweeteners has been altered so significantly during processing that allowance of a "natural" claim is exceedingly misleading, and contradicts USDA and CFIA standards.

Other examples of processes that fundamentally alter the raw ingredient follow:

Hydrogenation of oils alters the chemical and physical properties of the original vegetable oil. "Hydrogen is reacted with oil in the presence of a catalyst to combine with unsaturated fatty acids in the triglyceride molecule."¹⁶

Starch-based break down processes that manufacturer products used as bulking agents and texturizers, such as maltodextrin and modified food starch

Flour may be treated with an agent such as potassium bromate or chlorine dioxide during the milling process to purposely boost ingredient performance.

The resultant molecular alterations would preclude any claim of "natural" under USDA and CFIA standards.

¹⁴ *Id.* 58 Fed.Reg. 2407

¹⁵ "Guide to Food Labeling and Advertising, 4.7 Nature, Natural". Canada Food Inspection Agency, Accessed Dec. 14, 2005 at <http://www.inspection.gc.ca/english/fssa/labeli/guide/ch4ae.shtml>.

¹⁶ Hyu Y, H, Encyclopedia of Food Science and Technology, Vol 2 Fats and Oils: Chemistry, Physics and Applications pg 818-819 1992.

The Association contends that it is irrelevant whether the transformation process is controlled by chemical or enzymatic means. Identical types of breakdown products are created whether an acid, for example, or a specific hydrolytic enzyme is used.¹⁷ Purified single enzymes are simply catalysts that accelerate the rate of molecular degradation above that achievable with chemical systems.¹⁶ Regardless of whether hydrolysis is achieved by conventional chemical means or by enzyme catalysis, the molecular structure of the original substance is irreversibly altered.

The Association further contends that any process dependent on an enzyme extracted from a host organism is synthetic. Extracted enzymes differ substantively from the same enzyme that is an intrinsic component of a constituent system of enzymes within an intact biological organism. Extracted enzymes are themselves chemically changed when they are chemically attached to the backbone matrix of a commercial polymer structure and are manufactured specifically to chemically change a substance by the action of the immobilized enzyme. The *Organic Foods Production Act of 1990* defines the term "Synthetic" as "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes."¹⁸ Thus, any product manufactured from a process using extracted enzyme systems designed solely to increase efficiency of specialized molecular degradation remains a chemical process.

The USDA lists other processes that are considered relatively severe processes, such as solvent extraction, acid hydrolysis, and chemical bleaching. The CFIA provides the following processes that affect the natural character of a food by physical, chemical or biological changes.

- Anion exchange
- Bleaching (with chemical addition)
- Cation exchange
- Conversion (with chemical addition or synthesis)
- Curing (with chemical addition)
- Deboning (mechanical)
- Decaffeination (with chemical addition)
- Denaturation (with chemical change)
- Enzymolysis (with chemical addition)
- Esterification
- Hormonal action
- Hydrogenation
- Hydrolysis (with chemical addition)
- Interesterification
- Oxidation (with chemical addition)
- Reduction (with chemical addition)

¹⁷ Starch Hydrolysis Products: Worldwide Technology, Production and Application, FW Schenk and RE Hebeda, EDS. VCH Publishers, Inc. 1992. Chapters 3-6.

¹⁸ United States Department of Agriculture, Agriculture Marketing Service. 7 CFR Part 205, National Organic Program. §205.2

Smoking (with chemical addition)
Synthesis (chemical)
Tenderizing (with chemical addition)

The USDA definition,¹ while providing concise guidance for determining minimally processed, still permits some flexibility for making "natural" claims.¹⁹ The USDA definition provides for the following exceptions:

"Exceptions of this type 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 must be qualified to clearly and conspicuously identify the ingredient, e.g., —all natural or all natural ingredients except dextrose, modified food starch, etc."

Exists in Nature

Furthermore, a substance's mere presence in nature should not be a qualifying factor for a "natural" claim. When an ingredient or food component is manufactured by extraordinary processing means, the resultant product even if it exists somewhere in nature should not automatically qualify it as natural.

Degree of processing was a consideration in the National Advertising Division (NAD) of the Council of Better Business Bureau "Tom's of Maine" case (No. 3470 June 1, 1998) (Attachment One) in which NAD concluded that it was misleading for Tom's of Maine to advertise its product as natural. A competitor had questioned whether the product was natural based on one of the product's ingredients. While the manufacturer argued that the ingredient in question existed in nature, the NAD found this assertion was misleading because the ingredient in question underwent extensive processing to obtain the final product. Although this case involved mouthwash and not food, the principals are the same. NAD noted in its findings the significance of consumer expectations:

Given the target markets' significant interest in the naturalness of products ingredients, NAD believes that advertisers of "natural" products should be very specific when describing ingredients that may be inconsistent with their consumer expectations.

¹⁹ *Id.* USDA Food Standards and Labeling Policy Book. "All products claiming to be natural or a natural food should be accompanied by a brief statement which 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. This statement should 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.

The decision to approve or deny the use of a natural claim may be affected by the specific context in which the claim is made. For example, 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. However, —all natural ingredients might be an acceptable claim for such a product."

In two similar cases, NAD ruled that, while Procter & Gamble (Olean Fat Substitute), Report #3499, NAD Case Report (October 1, 1998) (Attachment Two) and Nutrasweet Company, Report #2490, NAD Case Report (April 20, 1987) (Attachment Three) did not directly advertise its products as natural, both companies advertising was misleading because there was an implied "natural" claim. The NAD reasoned that because consumers were only told that the products originated from a natural ingredient (P&G) or that as in Nutrasweet the components exist in nature, consumers could reasonably perceive that these products contain natural ingredients.

The Association contends that consumers' inherent lack of knowledge about food ingredients, food technology, food ingredient terminology and marketing claims places them at a disadvantage when trying to evaluate when a product or ingredient is natural. Therefore, consumers must rely on the oversight of regulatory agencies to provide food manufacturers with clear and concise regulations.

Again, a "natural" claim is exceedingly misleading if the final product is absent in the host plant or material from which it is manufactured, or the original chemical state has been altered significantly during processing. We assert that a criterion for the type and degree of processing (minimally processed) for making a "natural" claim is consistent with consumer expectations and the conclusions of respected review boards.

C.F.R. § 101.22: Definition of Natural and Artificial Flavors

In its 1991 NPR, FDA asked for comments seeking how the Agency could distinguish between artificial and natural flavors in § 101.22 under a minimally processed criterion. The USDA definition for a "natural" claim states, "Thus, the use of a natural flavor or flavoring in compliance with 21 CFR 101.22 which has undergone more than minimal processing would place a product in which it is used outside the scope of these guidelines."

Although the Association contends that in fair dealing with consumers, flavors that are more than minimally processed, especially flavors in which the process fundamentally changes the raw material, should not be categorized as natural. In its rulemaking, the CFIA did not establish guidelines for enzymatic flavors, processed flavors, reaction flavors or natural-identical flavors but instead agreed to examine each on a case-by-case basis.

Consumer Expectations and Understanding of "Natural" Claims on Foods and Beverages

FDA has stated that its objective is to find a meaningful definition for the term "natural" that the common consumer can understand.

To help identify what consumers understand and their expectation for products labeled as "natural", the Association commissioned Harris Interactive to conduct a nationally representative consumer survey (Attachment Four). First and foremost, when asked whether the government should provide food manufacturers with regulations to

follow when making a "natural" claim, 83% answered "yes" that the government should provide such regulations.

Eighty-five percent of the 1000 people surveyed said that they would not consider any food containing anything artificial or synthetic to be natural. Consumers also agreed that the amount of processing (52%) and/or altering of raw materials (60%) should disqualify a product from making a "natural" claim.

Further, when provided an overview of the USDA definition, 76% agreed these standards should be adopted to include all foods.

Therefore, the Association provides the following assertions to FDA as a basis to define natural as put forth in this petition:

1. The terms artificial and synthetic are generally well understood by consumers, but as acknowledged by FDA, misused in the marketplace. Consumers overwhelmingly believe a "natural" product should not contain any artificial or synthetic ingredients.
2. The majority of consumers do not consider a food or ingredient in which the fundamental raw material is altered through processing as "natural".
3. It is reasonable to expect that the majority of consumers can understand and would agree with the two criteria put forth in this petition for making a "natural" claim on foods or beverages - 1) a food that does not contain anything artificial or synthetic, and 2) a food or food ingredient is not more than minimally processed.

In Conclusion

A growing number of consumers have already made the value judgment that natural foods and ingredients are important when purchasing foods and beverages for themselves and their families. The Agency should put consumer interests first and promulgate comprehensive regulations to which food manufacturers must adhere before a claim of "natural" can be made on a food or beverage. This action would further promote honesty and fair dealings with consumers and further protect the public by ensuring that consumer expectations are met when purchasing a food or beverage that makes a "natural" claim.

C. ENVIRONMENTAL IMPACT

As provided in 21 C.F.R. § 15.30 neither an environmental assessment nor an environmental impact statement is required.

D. ECONOMIC IMPACT

As provided in 21 C.F.R. § 10.30(b) economic impact information is to be submitted only when requested by the Commissioner following review of the petition.

E. CERTIFICATION

The undersigned certifies that, to the best of their knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Andrew C. Briscoe III
President and CEO