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BY FIRST CLASS MAIL

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

Re: The Sugar Association Citizen Petition re Definition of the term  
"Natural" for making claims on foods and beverages regulated by  
the Food and Drug Administration [Docket No. 2006P-0094]

Dear Sir or Madam:

The Corn Refiners Association (CRA) submits these comments in response to the Sugar Association's citizen petition regarding a definition for the term "natural" for foods and beverages regulated by the U.S. Food and Drug Administration (FDA or the agency) (the Petition).<sup>1</sup> CRA is the national trade association representing the corn refining industry in the United States.<sup>2</sup> CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil, and feed products from corn components such as starch, oil, protein, and fiber. Corn sweeteners are the most important category of refined corn products, and supplied over 54 percent of the U.S.

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<sup>1</sup> The Sugar Association, Citizen Petition re Definition of the term "Natural" for making claims on foods and beverages regulated by the Food and Drug Administration (Feb. 28, 2006), Docket No. 2006P-0094/CPI (Petition), *available at* <http://www.fda.gov/ohrms/dockets/dockets/06p0094/06p-0094-cp00001-toc.htm>.

<sup>2</sup> Currently, CRA's member companies include Archer Daniels Midland Co., Cargill, Inc., Corn Products International, National Starch and Chemical Co., Penford Products Co., Roquette America, Inc., and Tate & Lyle Ingredients Americas, Inc.

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nutritive sweetener market in 2005.<sup>3</sup> Corn sweeteners include corn syrups, dextrose, high fructose corn syrup (HFCS), and crystalline fructose.

CRA opposes the Petition's request to define the term "natural" for FDA-regulated foods in accordance with the U.S. Department of Agriculture's (USDA) policy for "natural" claims in the labeling of meat and poultry products. FDA has clearly articulated and applied a reasonable and reliable policy for "natural" claims, which is consistent with consumer expectations and in accord with federal and international regulations and policies. The requested rulemaking would waste scarce agency resources to define a term that is subject to an existing and appropriate FDA labeling policy.

The Petition raises competitive concerns that are best resolved in the marketplace and not by regulation. The Petition advocates a definition for "natural" that would include sucrose but exclude other sugars, such as HFCS. This distinction is unjustified and inconsistent with FDA's settled policy for natural claims.

## **I. Introduction**

The Petition requests that FDA establish a regulation defining the term "natural" before such term may be used in food labeling. Specifically, the Sugar Association asks FDA to adopt the policy for "natural" claims employed by USDA for meat and poultry products. USDA's policy states the following, in relevant part:

### **Natural Claims:**

The term "natural" may be used on labeling for meat and poultry products, provided that 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 which do not fundamentally alter the raw product and/or which only separate

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<sup>3</sup> See Econ. Research Serv., U.S. Dept. of Ag., Sugar and Sweeteners: Data Tables, Table 49, available at <http://www.ers.usda.gov/Briefing/Sugar/data.htm>.

a whole intact food into component parts, e.g., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices....<sup>4</sup>

The Sugar Association asserts that FDA's adoption of USDA's policy for "natural" claims would maintain consistency across federal agencies, as well as "eliminate consumer confusion and minimize misleading claims."<sup>5</sup>

The first element in USDA's policy for "natural" claims for meat and poultry products is identical to FDA's existing policy for FDA-regulated foods. However, the Petition urges FDA also to adopt the second criterion of "minimal processing" for "natural" claims. The Sugar Association argues that the addition of this second criterion will "achieve[] a level of specificity that will negate much of the current ambiguity associated with a 'natural' claim."<sup>6</sup> The Petition interprets "minimally processed" to mean "processing that does not affect the natural character of the food or [the food's] molecular structure is identical to that present in the raw material from which it was physically separated." The Petition cites sugar from sugar cane or sugar beets as an example of a natural food ingredient, and identifies starch-based sweeteners, including HFCS, as examples of ingredients that are not natural. The Sugar Association argues that these products are not "natural" because "the final products are absent in the host plants from which they are manufactured," and their "original chemical state ... has been altered so significantly during processing that allowance of a 'natural' claim is exceedingly misleading ...."<sup>7</sup>

The Petition asserts that it is irrelevant to the application of the requested "natural" definition whether food processing involves chemicals or enzymes because both are unnatural. The Sugar Association argues that any enzymatic process is not natural if it involves an enzyme extracted from a host organism.<sup>8</sup> Finally, the Sugar Association contends that a substance's existence in nature should not be determinative of whether an ingredient or food is natural, especially when it is "manufactured by extraordinary processing means."<sup>9</sup>

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<sup>4</sup> Food Safety and Inspection Service, USDA, Food Standards and Labeling Policy Book, Natural Claims (August 2005), available at [http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling\\_Policy\\_Book\\_082005.pdf](http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf).

<sup>5</sup> Petition, *supra* note 1, at 1 and 4.

<sup>6</sup> Petition, *supra* note 1, at 5.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 6.

<sup>9</sup> *Id.* at 7.

CRA opposes the request that FDA define “natural” claims according to USDA’s policy. Since the 1980s, FDA has clearly articulated a policy for “natural” claims that is reasonable, well founded, and consistent with consumer understanding and expectations. In addition, contrary to the Sugar Association’s suggestion, FDA’s policy for “natural” claims is in accord with other federal and international regulations and policies.

The Sugar Association’s Petition is a thinly veiled attempt to obtain a marketing advantage for sucrose over HFCS. The Petition identifies starch-based sweeteners as examples of products that, according to the Sugar Association, should not be considered natural based upon their processing methods.

What the Sugar Association fails to disclose or explain is that the processing methods used to manufacture sweeteners like HFCS are comparable to those used to manufacture sucrose. There is no fundamental difference, in processing methods or otherwise, between sucrose and HFCS that would justify identifying one as natural and the other as unnatural. FDA should maintain its current policy for “natural” claims, which adequately and accurately informs consumers.

## **II. FDA Has Clearly Articulated and Consistently Applied A Reasonable Policy For “Natural” Claims**

FDA’s policy for “natural” claims provides that the agency will not restrict the use of the term “natural” *except* for added color, artificial or synthetic substances, and artificial flavors, as defined in 21 C.F.R. § 101.22. FDA has explained that “natural” means 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.”<sup>10</sup> The term may not be used for products with added color, synthetic or artificial substances, or artificial flavors (as defined by 21 C.F.R. § 101.22), because such use would be considered misleading.<sup>11</sup>

The FDA definition of “natural” is codified in the agency’s flavor labeling regulations. Under section 101.22(a)(3), a “natural flavor” is defined as

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,

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<sup>10</sup> 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). *See also, e.g.*, 56 Fed. Reg. 60421, 60466-67 (Nov. 27, 1991).

<sup>11</sup> *See, e.g.*, 62 Fed. Reg. 49826, 49841 (Sept. 23, 1997).

edible yeast, herb, bark, bud, root, leaf, or similar plant material  
.....<sup>12</sup>

By contrast, “artificial flavor” is defined, in relevant part, as “any substance the function of which is to impart flavor, *which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf, or similar plant material ...*”<sup>13</sup> Under these regulatory definitions, the distinction between “natural” and “artificial” is based primarily upon the source from which a food ingredient or product is derived (i.e., constituents of basic plant or animal foods) instead of the methods by which it is processed. The regulation for “natural flavors” explicitly encompasses such varied processing methods as extraction, hydrolysis, distillation, roasting, heating, and enzymolysis.

FDA’s policy for “natural” claims is well-established. The agency has applied the same policy since the 1980s, and has reconfirmed the policy in several subsequent rulemakings. During the early 1990s, in rulemaking under the Nutrition Labeling and Education Act of 1990 (NLEA),<sup>14</sup> FDA reiterated its policy without change.<sup>15</sup> Again, in 1997, in a final rule for nutrition and ingredient labeling requirements for dietary supplements, FDA explained that it

would maintain its policy not to restrict truthful and non-misleading use of the term [“natural”], except for products with added color, synthetic substances, or artificial flavors as provided in § 101.22, for which use of the term ‘natural’ on the label would be considered misleading.<sup>16</sup>

As recently as December 2005, only a couple of months before the Sugar Association submitted its Petition, FDA reconfirmed its policy.<sup>17</sup> FDA denied a citizen petition requesting

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<sup>12</sup> 21 C.F.R. § 101.22(a)(3).

<sup>13</sup> *Id.* at § 101.22(a)(1) (emphasis added).

<sup>14</sup> Pub. L. 101-535 (Nov. 8, 1990).

<sup>15</sup> *See* 56 Fed. Reg. at 60466-67; 58 Fed. Reg. at 2407.

<sup>16</sup> 62 Fed. Reg. at 49841.

<sup>17</sup> Letter from Margaret O’K. Glavin, Assoc. Comm’r Regulatory Affairs, FDA, to Antonio Zamora [Docket No. 2004P-0009/PDN1] (Dec. 12, 2005) (stating that FDA would “(1) ... not restrict the use of the term ‘natural’ except for added color, synthetic substances, and flavors as provided in 21 C.F.R. 101.22, and (2) ... regard the use of ‘natural’ as meaning that nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food.” FDA also explained that it would continue to distinguish between “natural” and “artificial” flavors as defined by regulation.).

that FDA redefine “natural” claims based upon processing methods. FDA found no reason to depart from its long established policy.<sup>18</sup>

The agency’s consistent application and enforcement of its policy for “natural” claims provides additional support for retaining the policy. In a 1988 case, FDA considered whether Canadian cod fillets containing sodium tripolyphosphate to retain moisture could be called “Natural Fillets.” Finding the claim objectionable, FDA explained that it is “not ... appropriate to use the term ‘natural’ when a product contains an added chemical that is not a constituent of the food since such term may be misleading.”<sup>19</sup> In a separate letter to USDA, FDA explained that it is “misleading to label a product as ‘natural’ if the product contains artificial colors, artificial flavors, chemical preservatives, or similar substances.”<sup>20</sup> In more recent examples, in warning letters to companies promoting foods that contained calcium chloride and citric acid as “all natural,” FDA reiterated its policy. In those cases, FDA explained that because “natural” means that “nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food .... the addition of calcium chloride and citric acid to these products preclude[s] use of the term ‘natural’ ....”<sup>21</sup>

In sum, FDA has consistently applied a reasonable policy for “natural” claims. FDA’s “natural” policy provides that a food labeled as “natural” does not contain any added color, artificial or synthetic substances, chemical preservatives, or artificial flavors (defined in 21 C.F.R. § 101.22) that would not normally be expected to be in the food.

### **III. FDA’s Policy Is Consistent With Consumer Expectations**

Contrary to the Sugar Association’s claims, FDA’s current “natural” policy is consistent with consumer expectations. The agency’s policy expressly accounts for consumer expectations

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<sup>18</sup> *See id.*

<sup>19</sup> Letter from Raymond E. Newberry, Acting Dir., Div. of Regulatory Guidance, CFSAN, FDA, to Clinton K. Davies, Ph.D., Dir. of Quality Assurance, Nat’l Sea Products, Inc. (Sept. 29, 1988).

<sup>20</sup> Letter from L. Robert Lake, Dir., Office of Compliance, CFSAN, FDA, to Cynthia H. Ford, Chief, Tech. Assistance Branch, Nutrition and Tech. Servs. Div., Food and Nutrition Serv., USDA (June 17, 1988).

<sup>21</sup> Warning Letter from Henry L. Fielden, Cincinnati District Dir., FDA, to Karl A. Hirzel, Hirzel Canning Co. (Aug. 29, 2001). *See also* Warning Letter from Robert L. Hart, Acting New York District Dir., FDA, to Richard Classey, Vice Pres. and General Mgr., Oak Tree Farm Dairy, Inc. (Aug. 16, 2001).

by providing that a food labeled as “natural” should not contain anything artificial or synthetic “that would not normally be expected to be in the food.”<sup>22</sup>

**A. The Evidence Cited In The Petition Does Not Support A Change In FDA’s Policy**

The Petition cites various articles to support the proposition that there has been significant growth in the marketing of natural foods and increased consumer interest in such products. However, there is no assertion in these articles that consumers are confused by “natural” claims. Thus, the articles cited in the Petition do not support any change in FDA’s food labeling policy for “natural” claims.

The Petition asserts that “all-natural” claims are the most “frequent ‘positive’ new product category.”<sup>23</sup> However, one of the articles identified in the Petition states that the claim “‘all-natural’ appears to be *slowing down*” while organic claims increase.<sup>24</sup> Another article cited in the Petition primarily focuses on organic claims, not natural claims. It explains that “[o]rganic will continue to take a growing share of the natural-organics sector as demand rises and more companies convert their products *from natural to organic*.”<sup>25</sup> A third article, entitled “Natural Products,” which cites an average 14 percent annual growth in the combined natural and organic foods categories, explains that “[o]rganic foods have been a key driver of this growth.”<sup>26</sup> This article also concludes that natural foods are projected to decline “as a result of many natural food producers and processors converting to organic.”<sup>27</sup> In sum, the references cited by the Sugar Association do not support the proposition for which they have been cited. More importantly, these articles provide no evidence that FDA’s current policy for natural claims is inappropriate.

The Petition includes a consumer survey purportedly showing that (1) consumers believe that a “natural” food should not contain artificial or synthetic ingredients; (2) “consumers do not consider a food or ingredient in which the fundamental raw material is altered through

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<sup>22</sup> See, e.g., 56 Fed. Reg. at 60466-67; 58 Fed. Reg. at 2407 (emphasis added).

<sup>23</sup> See Petition, *supra* note 1, at 3 nn. 6-8.

<sup>24</sup> A. Elizabeth Stone, “2005 Annual Meeting Expo Review New Product Trends,” *Food Technology* 59 no. 9, 36-44, at 40 (2005) (emphasis added).

<sup>25</sup> Food Marketing Institute, “FMI Backgrounder: Natural and Organic Foods,” at 6 (emphasis added), available at [http://www.fmi.org/media/bg/natural\\_organic\\_foods.pdf](http://www.fmi.org/media/bg/natural_organic_foods.pdf).

<sup>26</sup> John Norwood, “Natural Products,” Agricultural Marketing Resource Center, Iowa State Univ. (Jan. 2004) (emphasis added), available at <http://www.agmrc.org/NR/rdonlyres/61DAD87B-9BE8-41C0-8161-0391DD070917/0/naturalfoodsnorwood.pdf>.

<sup>27</sup> *Id.* at 1.

processing as ‘natural’; and (3) it is reasonable to expect that consumers understand and agree that “natural” should be defined as requested by the Sugar Association.<sup>28</sup> The first assertion is consistent with the FDA’s existing “natural” policy and is not disputed; however, the survey does not support the second or third assertions. According to the survey, there was a nearly even split in responses to the second question, with 52 percent answering that “processing matters for a natural claim” and 48 percent answering that it does not matter or that they do not know or are not sure. With regard to consumer beliefs about whether “processing that alters the raw material” should be permitted for “natural” claims, the survey question and example are flawed because they fail to disclose to respondents the origin of starch (e.g., from agricultural products) and how it is made into a sweetener. Finally, based on the survey, it is *unreasonable* to expect that consumers understand and agree that “natural” should be defined as proposed by the Petition. The question in the survey asked whether the USDA standards should be applied to all foods labeled as “natural.” The question is fundamentally flawed because it provides only one choice for survey respondents and fails to identify other reasonable options for defining the term “natural.”

**B. FDA’s Policy Is Consistent With Decisions Of The National Advertising Division**

FDA’s “natural” policy is consistent with decisions of the National Advertising Division (NAD) of the Council of Better Business Bureaus regarding “natural” claims. The NAD is the nation’s leading self-regulatory organization responsible for reviewing national advertising for truthfulness and accuracy.

In an early case, the NAD considered whether a television claim – “All natural ice cream. Still untouched by unnatural ingredients” – for Breyer’s Ice Cream was misleading. The ice cream product contained cream, whole or skim condensed milk, fresh milk, cane sugar syrup, water, and natural flavoring. The NAD concluded that the advertisement was substantiated based on the ingredients and that it contained no chemical preservatives, artificial flavors or colors.<sup>29</sup>

In a case involving Orbit Sugarless Gum, the NAD considered the following claim: “America’s leading dental organization recommends the all-natural sweeteners in Orbit sugarless gum.” The gum contained sorbitol and mannitol, which the advertiser, Wm. Wrigley Jr. Company, identified as “all-natural” sweeteners. Although the NAD initially questioned the accuracy of this characterization (because these ingredients are manufactured for commercial use

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<sup>28</sup> See Petition, *supra* note 1, at 8-9; Attachment 4 to the Petition.

<sup>29</sup> NAD Case Report, Special Report No. 3, at 1 (Oct. 1984) (discussing Kraft, Inc./Dairy Group, NAD Case No. 839 (published June 1979)).

from purified sugars), it ultimately accepted the claim. The NAD recognized that the claim was intended to distinguish nutritive sweeteners (which contain calories and are derived from naturally occurring carbohydrates) from non-nutritive, or man-made, sweeteners such as saccharin.<sup>30</sup> The NAD's decision clearly distinguished the gum's ingredients from artificial or synthetic substances which may not bear a "natural" claim under FDA's policy.

In a decision in 2000, the NAD considered whether an "all natural" claim on Eicotech Corporation's Zone Perfect Nutrition Bar was misleading. Eicotech argued that all of the ingredients in its nutrition bar meet the FDA's "natural" definition. The NAD concluded that the "all natural" claim was substantiated because "all of the products ingredients are characterized as 'natural' as defined by FDA's regulations."<sup>31</sup>

In these cases and others, the NAD's decisions are consistent with and support FDA's policy for "natural" claims. The NAD's expertise in consumer understanding is a primary factor in these decisions and serves to confirm the validity of FDA's "natural" policy for purposes of ensuring that consumer interests are protected.

#### **IV. FDA's Policy Is Consistent With Other Federal and International Regulations and Policies**

The Petition argues that FDA should maintain consistency across Federal agencies by defining "natural" in accordance with USDA's "natural" policy. However, claims for meat and poultry products implicate unique concerns. Moreover, the USDA policy was adopted informally without rulemaking or public participation.

The Sugar Association also argues that FDA's "natural" policy is inconsistent with Canada's policy for "natural" claims. However, the Petition fails to disclose that FDA's "natural" policy is consistent with other Federal and international regulations and policies for "natural" claims.

##### **A. FDA's Policy Is Consistent With The USDA Definition Of "Nonsynthetic (Natural)" Substances Under The USDA National Organic Program**

Under the Organic Foods Production Act of 1990 (OFPA),<sup>32</sup> USDA operates the National Organic Program (NOP) to develop and enforce uniform national standards for organically produced agricultural products. The OFPA and NOP regulations establish standards that must be

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<sup>30</sup> Wm. Wrigley Jr. Company: Orbit Sugarless Gum, NAD Case No. 1746 (Jan. 15, 1981).

<sup>31</sup> Eicotech Corp.: Zone Perfect Nutrition Bar, NAD Case No. 3632 (Mar. 1, 2000).

<sup>32</sup> Pub. L. 101-624, as amended by Pub. L. 109-97 (Nov. 10, 2005).

met to label a product with “organic” claims (e.g., “100% organic,” “organic,” and “made with organic ingredients”). Under the USDA regulations, “nonsynthetic” (or “natural”) substances are permitted in organic production and “synthetic” substances are generally prohibited.

The OFPA and NOP regulations both define “synthetic” as follows:

*Synthetic.* 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.<sup>33</sup>

“Natural” is defined by the NOP regulations as follows:

*Nonsynthetic (natural).* A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.<sup>34</sup>

The NOP’s definition of “natural” (or “nonsynthetic”) is consistent with FDA’s policy for “natural” claims. As reflected in the distinction between “artificial” and “natural” flavors in 21 C.F.R. § 101.22, FDA’s policy focuses upon the source from which a food ingredient or product is derived (i.e., constituents of basic plant or animal foods). “Natural flavors” may be derived from basic plant and animal sources,<sup>35</sup> just as “organic” foods must contain substances derived from mineral, plant, or animal matter.

Under FDA’s policy, the processes permitted for “natural” foods include methods such as extraction, hydrolysis, distillation, roasting, heating, and enzymolysis. The definitions for “natural” and “organic” both include foods or ingredients processed with enzymes. The fact that a biological process is commercially utilized for the efficient production of foods or ingredients does not render it a synthetic process for either “natural” or “organic” foods. Indeed, enzymes are expressly defined as “natural” substances under the NOP regulations and are permitted as ingredients in processed foods labeled with certain “organic” claims.<sup>36</sup>

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<sup>33</sup> 7 U.S.C. § 6502(21); 7 C.F.R. § 205.2 (emphasis added).

<sup>34</sup> 7 C.F.R. § 205.2.

<sup>35</sup> See 21 C.F.R. § 101.22(a)(3).

<sup>36</sup> See 7 C.F.R. § 205.605.

**B. FDA's Policy Is Consistent With The CODEX Definitions Of Natural Flavors**

FDA's "natural" policy is consistent with the CODEX Alimentarius Commission's (CODEX) guidelines and requirements for food labeling. Under the CODEX General Guidelines on Claims, a "natural" claim "should be used in accordance with the national practices in the country where the food is sold."<sup>37</sup> Additionally, the CODEX General Requirements for Natural Flavourings defines "natural flavors" and "natural flavouring substances" consistent with FDA's definition for "natural flavors." The CODEX definition provides:

Natural flavours . . . are preparations and single substances respectively, acceptable for known consumption, obtained exclusively by physical, microbiological or enzymatic processes from material of vegetable or animal origin in the raw state or after processing for known consumption by traditional food preparation processes (including drying, roasting and fermentation).<sup>38</sup>

Both the CODEX and FDA definitions focus on the source from which the food is derived (i.e., basic plant or animal components) and identify acceptable and similar processing methods. Both CODEX and FDA permit physical, microbiological or enzymatic processes, which include, for example, hydrolysis, distillation, roasting, heating, and enzymolysis, among others.

**V. There Is No Need Or Justification For A FDA Regulation Defining "Natural" Claims For Foods**

**A. FDA's Current Policy For "Natural" Claims Is Reasonable And Workable**

A regulation defining the term "natural" for food labeling is unnecessary because FDA's current policy is clear, well established, and reasonable. FDA has full authority to enforce its policy without issuing a regulation. FDA has a duty under section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act to take action against any false or misleading food labeling.<sup>39</sup>

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<sup>37</sup> Codex General Guidelines on Claims, CAC/GL 1-1979 (Rev. 1-1991; adopted by CODEX in 1979).

<sup>38</sup> General Requirements for Natural Flavorings, CAC/GL 29-1987 (adopted by CODEX in 1985).

<sup>39</sup> 21 U.S.C. § 343(a)(1).

**B. The Petition Provides No Compelling Reason For FDA To Revise Its Policy Or Initiate a Rulemaking to Limit “Natural” Claims**

FDA has repeatedly rejected requests to issue a regulation defining the term “natural” for food labeling and nothing in the Petition supports a change in FDA’s position.

In the early 1990s, in a rulemaking regarding nutrient content claims, FDA considered whether to define the term “natural” for foods and beverages. FDA reviewed definitions of other government agencies, states, and industry, focusing in particular on USDA’s “natural” policy. Recognizing that the various definitions were not consistent, FDA requested comments on whether and how it should proceed in defining “natural.”<sup>40</sup> In the final rule, FDA explained that none of the comments provided an adequate direction to develop a new definition for “natural.” Due to resource limitations and other priorities, FDA declined to define “natural” by regulation, and decided to maintain its existing policy.<sup>41</sup>

As recently as last year, FDA reconfirmed its “natural” policy. In 2005, a citizen petition requested FDA to limit “100% Natural” and “All Natural” claims to unaltered ingredients found in nature. The petition asked that these claims only be permitted for components of a natural product obtained through physical processes of isolation or refinement, excluding any processes that alter the chemical composition of the natural components (except for the application of heat for cooking, baking, or toasting). As it did in 1993, FDA denied the petition, explaining that it was not persuaded to alter its existing policy.<sup>42</sup>

The Sugar Association has not provided any new or compelling reason to alter FDA’s existing policy for “natural” claims.

**C. The Sugar Association Petition Is Based Upon Competitive Concerns, Not Consumer Interests**

The Petition is a transparent attempt by the Sugar Association to shift food labeling policies to favor sucrose over other sweeteners such as HFCS, and to increase the market share of sucrose. This type of competitive purpose does not merit the initiation of an expensive and resource intensive rulemaking process.

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<sup>40</sup> 56 Fed. Reg. at 60466-67.

<sup>41</sup> 58 Fed. Reg. at 2407.

<sup>42</sup> Letter from Margaret O’K. Glavin, Assoc. Comm’r Regulatory Affairs, FDA, to Antonia Zamora [Docket No. 2004P-0009/PDN1] (Dec. 12, 2005).

Since the 1960s, there has been a dramatic shift from the use of sucrose to sweeteners manufactured through starch hydrolysis, including corn sweeteners, in many food products.<sup>43</sup> In the mid-1950s, new technology used to purify and crystallize dextrose allowed corn-based sweeteners, for the first time, to compete in some markets that had been the sole domain of the sugar (sucrose) industry. Subsequent developments involving enzyme catalyzed isomerization of dextrose to fructose led to HFCS. In recent decades, there has been increased use of HFCS and other corn sweeteners in lieu of sucrose.<sup>44</sup> Contrary to the Petition's claims, there is no reasonable basis to distinguish sucrose from HFCS or other starch-based sweeteners by redefining the term "natural." The Sugar Association's desire to regain lost market share does not provide a legitimate basis for revising the existing "natural" policy or initiating a rulemaking to redefine the term.

**D. A Rulemaking Process To Define "Natural" Would Waste Scarce FDA Resources**

A rulemaking to define the term "natural" would waste scarce FDA resources that would otherwise be devoted to more important agency activities. For its 2006 Program Priorities, FDA's Center for Food Safety and Applied Nutrition (CFSAN) identified five overarching goals: ensuring food defense, ensuring food safety, improving nutrition, ensuring dietary supplement and cosmetic safety and management services, and accomplishing priority ongoing activities.<sup>45</sup> A rulemaking to define "natural" would not advance any of these goals.

**VI. HFCS Is Properly Regarded As A Natural Product**

- *HFCS is predominantly composed of glucose and fructose.*

HFCS is composed predominantly of the monosaccharides glucose and fructose, which are found in many foods which occur in nature. HFCS, sucrose, invert sugar, honey, and many fruits all contain fructose and glucose. The ratio of fructose to glucose in all of these products is

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<sup>43</sup> See, e.g., CRA, "The History of Corn Refining, A Brief History of the Corn Refining Industry," available at <http://www.corn.org/historycornrefining.htm>.

<sup>44</sup> See generally CRA, "Sweeteners," available at <http://www.corn.org/web/sweeten.htm>. For more information about market trends for sucrose and corn sweeteners, see Econ. Research Serv., U.S. Dept. of Ag., Briefing Room: Sugar and Sweeteners, available at <http://www.ers.usda.gov/Briefing/Sugar/>.

<sup>45</sup> CFSAN/FDA, CFSAN 2006 Program Priorities (May 3, 2006), available at <http://www.cfsan.fda.gov/~dms/cfsan506.html>. See also 71 Fed. Reg. 37083 (June 29, 2006) (requesting comments on the same goals for FDA's 2007 program priorities).

roughly 1:1. In addition, trace elements (minerals) found in HFCS are identical to those found in many foods which occur in nature.

- ***The composition of HFCS is nearly identical to sucrose.***

Sucrose and HFCS are nearly identical in composition. The ratio of glucose to fructose in HFCS approximates the amount of fructose and glucose comprising sucrose extracted from botanical sources (cane and beet).

The only difference between the composition of HFCS and sucrose is their chemical structure. In the sucrose molecule, fructose and glucose are held together with a glycosidic bond as a disaccharide, whereas in HFCS, the fructose and glucose are free (i.e., they are not bonded together but exist as monosaccharides). In the small intestine, sucrose is “enzymatically cleaved ... to yield one molecule each of fructose and glucose.” HFCS does not require such enzymatic hydrolysis because it is already composed of free glucose and fructose. In some cases, even this difference does not exist:

Although sucrose is a disaccharide, it hydrolyzes to its monosaccharide components in acid media (such as in most sweetened carbonated beverages and lemonade). The extent of hydrolysis is dependent on time, temperature, and pH. By the time they are consumed, many sucrose-sweetened carbonated beverages may, in fact, contain significant amounts of free glucose and fructose and, therefore, closely resemble HFCS in this respect.<sup>46</sup>

When sucrose does maintain the glycosidic bond as a disaccharide, it makes very little metabolic difference when consumed. Sucrose is rapidly hydrolyzed to monosaccharides by an enzyme in the small intestines. Once in the bloodstream, monosaccharides derived from HFCS, sucrose, honey, and fruit appear to be metabolized identically using well-characterized metabolic pathways.<sup>47</sup> The difference between free or bonded fructose and glucose in HFCS and sucrose, respectively, simply gives the two sweeteners different functional properties in foods and beverages.

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<sup>46</sup> Marilyn D. Schorin, “High Fructose Corn Syrups, Part 1: Composition, Consumption, and Metabolism,” *Nutrition Today*, Vol. 40, No. 6, at 2248-52 (Nov./Dec. 2005).

<sup>47</sup> See CRA, “Questions and Answers About High Fructose Corn Syrup” (citing A.M. Coulston & R.K. Johnson, “Sugar and sugars: Myths and realities,” *J. Am. Diet Ass’n.* 102(3):351-53 (2002); M. Sigman-Grant & J. Jorita, “Defining and interpreting intakes of sugars,” *Am. J. Clin. Nutr.* 78(4):815S-826S (2003)), available at <http://corn.org/HFCSBrochure.pdf>.

- ***HFCS is derived from nature.***

HFCS is processed directly from corn, an agricultural food.

- ***HFCS is naturally processed.***

HFCS is not only derived from natural grain crops (corn), but it is processed through mechanical means with the use of natural bio-catalysts, or enzymes.

- ***HFCS is produced by processes explicitly permitted for use in "natural flavors."***

The FDA regulatory definition of "natural flavors" explicitly includes products produced by processes such as hydrolysis and enzymolysis which are used in production of HFCS. The processing of HFCS is consistent with processes permitted for "natural flavors," which supports the conclusion that HFCS is naturally processed from a natural source.

- ***HFCS contains no artificial or synthetic substances.***

The crux of FDA's "natural" policy is that a product labeled as "natural" may not contain any artificial or synthetic substance that would not normally be expected to be in the food. As previously explained, HFCS is principally composed of the monosaccharides glucose and fructose, with a small remainder being polysaccharides. It is processed by mechanical and natural (enzymatic) methods. Nothing in the source or processing of HFCS introduces an artificial or synthetic substance to HFCS that renders it unnatural. Nor does HFCS contain any color additives.

- ***HFCS qualifies as a "nonsynthetic (natural)" substance under the USDA NOP.***

As previously explained, under the OFPA and USDA's NOP regulations, HFCS qualifies as a nonsynthetic (natural) substance. The NOP regulations expressly define enzymes as natural and permit their use in certain organic foods. Because HFCS is derived from corn and does not undergo a synthetic process, it satisfies the USDA NOP's definition of "natural."

- ***HFCS is an appropriate ingredient in natural foods and one that consumers would normally expect to be in natural food products.***

HFCS is typically used as a sweetener in processed food products. Examples of products in which HFCS is commonly used and in which consumers would recognize its use include carbonated soft drinks, breakfast cereals, fruit juices, sauces and dressings, snack foods such as crackers, pretzels, and granola bars, ice cream, jams and preserves, and canned soups, among others. Assuming that a product otherwise satisfies the criteria for "natural" claims, the addition of HFCS would not preclude the use of such claim. The inclusion of HFCS as an ingredient in

such foods does not confuse or mislead consumers because there is a long history of use of HFCS in foods marketed as “natural.”

**VII. FDA Should Not Adopt A “Minimally Processed” Requirement For “Natural” Claims**

FDA should not adopt a “minimally processed” criterion for “natural” claims. There is no consensus regarding the meaning of this criterion, nor is it appropriate for manufactured or processed foods.

**A. There Is No Consensus Or Common Understanding Regarding The Term “Minimally Processed”**

FDA has previously questioned the meaning of the term “minimally processed.”<sup>48</sup> There is no consensus or common understanding about the meaning of this term. Even USDA’s “natural” policy reflects confusion regarding the meaning of “minimally processed.” Under USDA’s policy, “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 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.<sup>49</sup>

The policy goes on to explain that the use of a “natural flavor” that complies with FDA’s regulation in 21 C.F.R. § 101.22 would place it outside the scope of USDA’s policy if the flavoring has undergone more than minimal processing. However, in its own regulations, USDA defines “natural flavors” identical to FDA’s definition.<sup>50</sup>

Canada appears to be the only other official or governmental body that has attempted to define “minimal processing” for purposes of “natural” claims in food labeling. Canada has instructed food processors that “[c]laiming that a product is ‘natural’ in Canada is not permitted

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<sup>48</sup> 56 Fed. Reg. at 60466-67; 58 Fed. Reg. at 2407.

<sup>49</sup> See Food Safety and Inspection Service, USDA, Food Standards and Labeling Policy Book, Natural Claims, *supra* note 4.

<sup>50</sup> Cf. 21 C.F.R. § 101.22 (FDA’s “natural flavor” definition) and 9 C.F.R. §§ 317.2(f)(1)(i)(B) and (ii); 381.118(c) (USDA’s definitions for “natural flavor” for meat and poultry products).

...although it is acceptable to claim that a food contains ‘natural ingredients.’”<sup>51</sup> The Canadian Food Inspection Agency (CFIA) has established guidance on the use of “natural” claims, explaining that

Foods or ingredients of foods submitted to processes that have significantly altered their original physical, chemical or biological state should not be described as “natural.”<sup>52</sup>

Canada’s guidelines list processes the CFIA considers to have minimum and maximum effects on foods or ingredients. The list is not consistent with processing methods permitted for “natural flavors” under FDA’s regulation, USDA’s “natural” policy, or the USDA NOP.

In view of the inconsistencies in and between the only two existing definitions for “minimal processing” and the lack of a clear definition of the term by any scientific or governmental body, “minimal processing” should not be adopted by FDA as a requirement for “natural” claims.

**B. The USDA “Minimally Processed” Requirement Applies To A Special Category Of Products**

There is a fundamental difference between USDA- and FDA-regulated food products. Meat and poultry products regulated by USDA are typically understood to be less processed than foods regulated by FDA. USDA-regulated meat and poultry products are more suitable for a “minimally processed” criterion, if one is to be applied to foods at all, because these products are generally less processed or manufactured than many FDA-regulated foods. Moreover, because it reviews and approves labels for meat and poultry products prior to market,<sup>53</sup> USDA is in a position to maintain appropriate flexibility in the application of its “natural” policy. Labeling for FDA-regulated foods does not undergo premarket review and approval. If FDA were to incorporate a “minimally processed” criterion into a definition of “natural” by regulation, the food industry would lose important flexibility in making truthful and accurate claims about the nature of their products.

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<sup>51</sup> See Agriculture and Agri-Food Canada, Agri-Food Trade Service, “Nutrition and Health Labeling Claims in the US” (Dec. 2005), *available at* [http://atn-riac.agr.ca/us/4083\\_e.htm](http://atn-riac.agr.ca/us/4083_e.htm).

<sup>52</sup> CFIA, Guide to Food Labeling and Advertising § 4.7, “Nature, Natural,” *available at* <http://www.inspection.gc.ca/English/fssa/labeti/guide/ch4ae.html>.

<sup>53</sup> See 9 C.F.R. § 317.4.

**C. A “Minimally Processed” Requirement Cannot Reasonably Be Applied to Manufactured Foods**

Under the definition advocated in the Petition, sucrose itself would be considered more than minimally processed. The Sugar Association argues that “[w]hen 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.”<sup>54</sup> Based on its interpretation of “minimally processed,” the very product it seeks to protect and promote, sucrose, arguably would not qualify as “natural.” Sucrose production from either sugar cane or sugar beets requires extensive processing.

For example, sucrose production from sugarcane involves several steps. Once sugar cane is milled to extract the juice, the cane juice is strained and clarified:

[C]larification is done almost exclusively with heat and lime (as milk of lime or lime saccharate); small quantities of soluble phosphate may also be added.... A heavy precipitate forms .... called “mud,” [and] is separated from the limed juice by gravity or centrifuge....

Evaporation is the next step, which occurs in an evaporator station and then vacuum pans. The syrup is then clarified again by adding lime, phosphoric acid, and a polymer flocculent, then aerated and filtered. To crystallize the sugar, some mills seed the vacuum pans with isopropyl alcohol and ground sugar. Once the sugar crystals are dried and cooled, the sugar is again refined by washing and clarification:

Two clarification methods are commonly used: pressure filtration and chemical treatment; chemical clarification is the preferred method. Two chemical methods are commonly used: phosphatation and carbonation; both processes require the addition of lime.... The next step is decolorization .... The two most common adsorbants are granular activated carbon and bone char, manufactured from degreased cattle bones....

The decolorized sugar liquor is moved through heaters, multiple effect evaporators, vacuum pans, and then ultimately “seeded” to form crystals. Next, the crystals are washed in a centrifuge and then dried, screened, conditioned, and stored until packaging.<sup>55</sup> The refined cane sugar may

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<sup>54</sup> See Petition, *supra* note 1, at 7.

<sup>55</sup> See generally Environmental Protection Agency, AP 42, Compilation of Air Pollutant Emission Factors, Vol. 1, § 9.10.1.1 Sugarcane Processing (5th ed.), *available at* (continued...)

be further processed into invert sugar by dissolving it in water to make liquid sucrose, and then adding hydrochloric acid and sodium hydroxide, or enzymes to hydrolyze the bond between glucose and fructose.<sup>56</sup>

Sucrose from sugar beets is processed by similarly extensive methods. Once sugar beets are cleaned and washed, they are sliced into long strips that are conveyed to diffusers to extract sucrose:

Sulfur dioxide, chlorine, ammonium bisulfite, or commercial FDA-approved biocides are used as disinfectants. The sugar-enriched water that flows from the outlet of the diffuser is called raw juice .... [which] proceeds to the juice purification operations....

During the purification process, impurities are removed from the raw juice through the following steps:

First the juice passes through screens ....[t]hen the mixture is heated ... and proceeds to the first carbonation tank. In some processes, the juice from the screen passes through a pre-limer, heater, and the main limer prior to the first carbonation tank. In the first carbonation tank, milk of lime [ $\text{Ca}(\text{OH})_2$ ] is added ... and carbon dioxide ( $\text{CO}_2$ ) gas is bubbled through the mixture to precipitate the lime as insoluble calcium carbonate crystals.... The small, insoluble crystals ... settle out in a clarifier, after which the juice is again treated with  $\text{CO}_2$  (in the second carbonation tank) to remove the remaining lime and impurities.... After filtration, a small amount of sulfur dioxide ( $\text{SO}_2$ ) is added to the juice to inhibit reactions that lead to darkening of the juice.... Following the addition of  $\text{SO}_2$ , the juice ... proceeds to the evaporators.

The evaporation process is usually performed in a series of five evaporators. Crystallization is the next step and begins with low-temperature boiling in vacuum pans. Crystal formation is

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<http://www.epa.gov/ttn/chief/ap42/ch09/final/c9s10-1a.pdf>. See also J.H. Galloway, "History of sugar – Domestication to the 17th Century," abstracted from *Annals of the Ass'n of Am. Geographers*, Vol. 86, No. 4, at 682-706 (Dec. 1996), available at <http://home.wlu.edu/~powc/intr132/sugar.html>; C.C. Chou, "Sugar refining processes and equipment," in *Handbook of Sugar Refining: A Manual for the Design and Operation of Sugar Refining Facilities* (2000).

<sup>56</sup> See Lantic Sugar, Canada, "Overview of sugar refining at Montreal processing plant," available at <http://www.lantic.ca/English/overview/montreal.html>.

usually achieved by either shocking the syrup with powdered sugar or seeding it with a mixture of sugar and isopropyl alcohol. Next, the crystals are moved to a mixer and then poured into high-speed centrifuges for separation. They are washed, sent to the granulator for drying and cooling, screened, and then either packaged or stored.<sup>57</sup>

As the above-described procedures demonstrate, the extent of processing required for sucrose production (from sugar cane and sugar beets) is surely more than “minimal.”

Even USDA has recognized that sucrose is more than minimally processed. Otherwise, it would not have carved out an exception for sugar at the end of its current policy (i.e., “Note: Sugar ... [is] acceptable for – all natural claims”). In fact, USDA once expressly identified sucrose as more than minimally processed. In USDA’s Policy Memo 055 that first defined “natural” claims, USDA did not include an exemption for “sugar.” Instead, its instruction about qualifying a “natural” claim to identify an unnatural ingredient specifically used sucrose as an example:

[T]he 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., contains refined sugar.<sup>58</sup>

USDA updated its policy in 2005 to remove this reference and create an exemption for sucrose.<sup>59</sup> However, even advocates of the Sugar Association’s Petition have admitted that sucrose is refined by extensive processes.<sup>60</sup>

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<sup>57</sup> See Environmental Protection Agency, AP 42, Compilation of Air Pollutant Emission Factors, Vol. 1, § 9.10.1.2 Sugarbeet Processing (5th ed.), available at <http://www.epa.gov/ttn/chief/ap42/ch09/final/c9s10-1b.pdf>.

<sup>58</sup> USDA Food Labeling Division Policy Memoranda, Policy Memo 055 from Robert G. Hibbert, Dir., SLD, to Branch Chiefs, SLD (Nov. 22, 1982).

<sup>59</sup> See Food Safety Inspection Service, USDA, Food Standards and Labeling Policy Book, *supra* note 4.

As noted, FDA has previously considered and rejected a “minimally processed” criterion. The agency explained that multiple definitions of “minimal processing” were proposed in comments, and that there are “many facets of this issue” that the agency would have to carefully consider before it could attempt to define “natural” to include this criterion.<sup>61</sup>

Further, even the Codex Alimentarius Commission has declined to adopt a “minimally processed” requirement for “natural” claims in food labeling. In 1993, CODEX considered revising its General Guidelines on Claims to include new definitions for claims such as “Natural (Naming the Food)” and “(Naming the Food) is a Natural Food.” In 1994, Canada prepared and circulated an amendment proposing that these “natural” claims be limited to foods which “exist in nature and which have undergone no or minimal processing [and] do not contain food additives or added vitamins, minerals, colours or flavours.” The proposal defined “minimal processes” as “those processes which do not fundamentally change the original character of the food or those need to make the food fit for human consumption.”<sup>62</sup> These changes were never adopted. CODEX rejected them in favor of allowing “natural” claims to be regulated by the country in which a “natural” food is sold.<sup>63</sup>

#### **D. There Are Significant Differences Between Enzyme Versus Chemical Processes**

In the Petition, the Sugar Association asserts that it is “irrelevant” to a “natural” claim whether processing “is controlled by chemical or enzymatic means.” This is clearly not the case, and should not serve as a basis for defining “natural” claims. By eliminating foods processed with enzymes from the definition of “natural,” the sugar industry seeks a definition of “natural” that would be exclusive to sucrose. However, even the sugar industry utilizes enzymes during the processing of sucrose, including for inversion and as filtration and crystallization aids.<sup>64</sup>

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<sup>60</sup> CSPI’s Petition for the Initiation of an Investigation and the Issuance of a Complaint, to Office of the Secretary, FTC, at 2 (Feb. 20, 1980) (“In fact, fructose is refined by a process at least as extensive as that used to produce ordinary sugar.”).

<sup>61</sup> See 58 Fed. Reg. at 2407.

<sup>62</sup> Joint FAO/WHO Food Standards Programme, Codex Cmte. on Food Labelling (23rd Sess.), Agenda Item 7, Proposed Draft Amendment to the General Guidelines on Claims on the Use of the Term “Natural” (Oct. 24-28, 1994).

<sup>63</sup> Codex General Guidelines on Claims, CAC/GL 1-1979 (Rev. 1-1991; adopted by CODEX in 1979).

<sup>64</sup> John S. White, Invited Presentation of “HFCS Myths,” at Managing Sweetness: International Scientific & Communications Conference (Mexico City, Nov. 2004). See also, e.g., Martin (continued...)

Contrary to the Sugar Association's position, there are significant differences between foods produced through enzymatic versus chemical means. The conversion of starch to various products used in foods, including HFCS, involves starch hydrolysis. Initially, starch hydrolysis was performed with heat and acid treatment of starch. "While effective, these methods were not specific, and undesirable by-products and off-flavors were also formed as a result of the harsh reaction conditions."<sup>65</sup> When enzymes were introduced to replace older heat and acid methods, their use led not only to better controlled processes, but to fewer by-products in the final product.<sup>66</sup> In essence, enzymatic hydrolysis substantially reduces undesirable side reactions such as degradation, color, off-flavor, and unwanted materials in the final product.<sup>67</sup> Moreover, nothing is more natural than processing foods with the fundamental catalysts of chemical reactions in living systems.

FDA has clearly recognized the differences between chemical and enzymatic processing. Under its regulation for "natural" flavors, the agency permits enzymolysis for "natural flavors."<sup>68</sup> In addition, in its application and enforcement of its "natural" policy, FDA has only prohibited "natural" claims for products subject to chemical processes. For example, in a rulemaking for dietary supplement labeling, the agency has advised that

the term "natural" should not be used when referring to a vitamin that is only obtained through *chemical synthesis* (e.g., use of 'natural vitamin E' for a product containing dl-alpha tocopherol acetate)."<sup>69</sup>

In another example, the agency considered whether certain coffee decaffeination processes were natural. In that case, coffee was decaffeinated using ethyl acetate derived from acetaldehyde, acetic acid, and ethanol. FDA concluded that "coffee that has been decaffeinated with the use of a chemical extractant, including ethyl acetate ... may not be represented as being 'natural

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Chaplin & Christopher Bucke, *Enzyme Technology*, Ch. 4, "Enzymes in the Sucrose Industry" (Cambridge Univ. Press 1990), *available at* <http://www.lsbu.ac.uk/biology/enztech/index.html>.

<sup>65</sup> W. Martin Teague & Phillip J. Brumm, "Commercial Enzymes for Starch Hydrolysis Products," at 45, *in* *Starch Hydrolysis Products: Worldwide Technology, Production and Applications* 45-77 (Schenk, F.W. & Hebeda, R.E., eds. 1992).

<sup>66</sup> *Id.*

<sup>67</sup> See John S. White, "Fructose Syrup: production, properties and applications," at 178, *in* *Starch Hydrolysis Products: Worldwide Technology, Production and Applications* 177-99 (Schenk, F.W. & Hebeda, R.E., eds. 1992).

<sup>68</sup> See 21 C.F.R. § 101.22(a)(3).

<sup>69</sup> 62 Fed. Reg. 49826, 49841 (Sept. 23, 1997) (emphasis added).

decaffeination' or 'naturally decaffeinated.'"<sup>70</sup> The agency reasoned that such claims would be misleading because they fail to reveal material facts that "caffeine has been extracted by *chemical* means."<sup>71</sup>

Furthermore, many foods which are generally regarded as natural foods routinely use added enzymes in their processing. For example, enzymes are added during fruit juice processing to remove (through enzymatic hydrolysis) cloudiness caused by pectins.<sup>72</sup> One of the best known examples of enzyme processing is the use of rennet (mainly chymosin – from unweaned calves) in the production of cheese. Today, calf rennet has been replaced by cheaper enzyme alternatives from microbial sources. Other enzymes, proteases and lipases, may also be used in cheese production to promote flavor.<sup>73</sup>

The above examples demonstrate that there are important differences between processing using chemical versus enzymatic means, which are recognized and supported by FDA.

#### **VIII. FDA Should Maintain Its Current Policy And Consider "Natural" Claims On A Case-By-Case Basis**

The appropriateness and accuracy of a "natural" claim depends upon the context in which it is made. The Federal Trade Commission (FTC or the Commission) regularly considers the context of claims in its determinations whether advertising is false or misleading. Indeed, the Commission has long applied this approach for "natural" claims.

In the 1970s, FTC proposed to define "natural foods" as those with no artificial ingredients and only minimal processing.<sup>74</sup> After much consideration, however, the Commission terminated the rulemaking and elected to evaluate "natural" claims on a case-by-case basis instead, explaining:

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<sup>70</sup> Letter from Nina L. Adler, Div. of Programs and Enforcement Policy, Office of Food Labeling, FDA, to Mr. Timothy P. O'Shea, Haight, Gardener, Poor & Havens, (Feb. 22, 1994).

<sup>71</sup> *Id.* (emphasis added).

<sup>72</sup> Martin Chaplin & Christopher Bucke, *Enzyme Technology*, Ch. 4, "Enzymes in the fruit juice, wine, brewing and distilling industries," *supra* note 64.

<sup>73</sup> *Id.* at Ch. 4, "Applications of proteases in the food industry."

<sup>74</sup> Minimal processing was never clearly defined by the Commission, but the preamble to the proposed rule suggested that it could mean processes which changed the physical form of the food, heat processing, or other sterilization processes. *See* 39 Fed. Reg. 39842, 39849 (Nov. 11, 1974); 40 Fed. Reg. 23086 (May 28, 1975); 41 Fed. Reg. 8980, 8982-83 (Mar. 2, 1976).

Quite aside from the significant difficulties that would be posed in enforcing this rule, a fundamental problem exists by virtue of the fact that the context in which “natural” is used determines its meaning. It is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream. The proposed rule assumes, without any evidence, that ‘natural’ means the same thing in every context. We should concentrate our resources on more serious consumer protection problems than addressing whether a claim that ‘milk is natural’ is deceptive.”<sup>75</sup>

In 1991, during rulemaking for nutrient content claims, FDA acknowledged the Commission’s approach and recognized that the FTC declined to issue a prescriptive definition for the term “natural.”<sup>76</sup> At that time, FDA also declined to further limit the term “natural” and chose to maintain its current policy.

“Natural” claims are more appropriately regulated on a case-by-case basis, with consideration of the nature of the labeled food and context of the claim. An overly prescriptive definition could bar some foods from bearing the claim that are otherwise properly regarded as natural foods. FTC’s decision not to define “natural” was based on a determination that a rule “should be promulgated only when there is evidence that the problems it addresses are so widespread that the benefits of the rule justify the regulatory burdens it would impose.”<sup>77</sup> Just as there was no overriding reason to define “natural” by regulation then, there is none today.

Based upon these considerations, FDA should maintain its current policy for “natural” claims. “There is well established precedent that the reasonable takeaway of an advertisement [or claim] requires the evaluation of the entire advertisement [or labeling] instead of the meaning of words or phrases standing alone.”<sup>78</sup> Moreover, this approach ensures that the protections of the First Amendment remain intact for the food industry. To narrowly define the term “natural” by regulation could unconstitutionally infringe on a food producer’s right to accurately communicate the nature or character of its products and/or qualify or explain the label claim.

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<sup>75</sup> 48 Fed. Reg. 23270 (May 24, 1983).

<sup>76</sup> 56 Fed. Reg. at 60467.

<sup>77</sup> 48 Fed. Reg. 23270.

<sup>78</sup> Sanderson Farms: Sanderson Farms Chicken, NAD Case No. 4289, at 15 (Mar. 8, 2005) (citing *Pizza Hut, Inc. v. Papa John’s*, 227 F.3d 489, 495 (5th Cir. 2000), *cert. denied*, 2001 U.S. Dist. LEXIS 2195 (Mar. 19, 2001)); *American Home Products Corp. v. FTC*, 695 F.2d 681, 687 (3d Cir. 1982).

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**IX. Conclusion**

The Petition should be denied. FDA has consistently articulated and applied a clear and rational policy for the use of "natural" claims in food labeling. A "minimally processed" requirement is not necessary to ensure that foods labeled as "natural" convey truthful and not misleading information to consumers. FDA should continue to apply on a case-by-case basis the reasonable and appropriate policy it has consistently maintained for "natural" claims in food labeling.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Audrae Erickson".

Audrae Erickson  
President