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Dr. Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
Division of Dockets Management
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted via the Federal eRulemaking Portal

Re: Docket No. FDA-2014-N-1207-1827
Use of the Term "Natural" in the Labeling of Human Food Products;
Request for Information and Comments

Dear Dr. Califf,

The New York Attorney General ("NYAG") welcomes the opportunity to submit comments on the use of the term "natural" in the labeling of human food products. We believe a federal definition is sorely needed and urge the Food and Drug Administration ("FDA") to promulgate a definition that will end the existing confusion and misleading use of the term "natural" in the labeling of such products.

The food industry's use of the term "natural" in labeling and marketing has long confused consumers, whose expectations and experience of what constitutes "natural" is often at odds with practices of manufacturers and advertisers. Moreover, an enormous increase in industrialized agriculture and food processing has coincided with the proliferation of "natural" claims on food labels and in advertising. As a result, there has also been extensive litigation challenging the use of "natural" as deceptive and misleading, and courts have been left to grapple with these issues with little federal regulatory guidance. This uncertainty costs both consumers and the industry millions of dollars. Consumers pay more for deceptively advertised products that lack the benefits they seek, and those in the food industry who have invested in accurate and honest labeling are placed at a competitive disadvantage by those who inaccurately or deceptively market products as natural.[1] FDA's current informal policy, published as an

[1] Stephen Gardner, Amanda Howell, and Erika Knudsen, *FDLI's Food and Drug Policy Forum: A Natural Solution: Why Should FDA Define "Natural" Foods?*, THE FOOD AND DRUG LAW INSTITUTE, Vol. 4, Issue 9, Sept. 24, 2014.

advisory opinion more than twenty years ago, is non-binding and not legally enforceable. A federal definition of "natural" would provide much needed guidance to the industry as well as to courts and law enforcement officials.

A federal definition would also contribute to consumers' consistent and accurate understanding of the term. Although it may not be possible for a federal definition to encompass all ingredients and processes produced by rapidly changing technologies, maintaining the status quo, which includes the food industry's efforts to label thousands of products as natural, even some that are highly processed or contain synthetic ingredients, is not an option.

FDA can fill this void by promulgating a definition that provides uniformity and consistency in the use of the term "natural." The NYAG does not believe that the use of the term "natural" should be banned outright. A ban would be unfair to industry members who have developed foods that provide the types of ingredients consumers seek and deprive consumers of the ability to purchase products that are in accord with their expectation of what "natural" should mean. Consumers' growing interest in and willingness to purchase and pay more for natural foods further underscores the need for a uniform and consistent federal definition.

Widespread Consumer Confusion Regarding the Term "Natural"

There is widespread confusion among consumers about what the term "natural" means. Surveys demonstrate that the often indiscriminate use of the word natural, accompanied by depictions of farms or other bucolic settings, leads to consumer misperception that natural is not only a healthier choice than foods not so labeled, but that natural foods are "better" or "healthier" than other foods, including those that bear the United States Department of Agriculture ('USDA") organic certification label.

Several consumer surveys conducted by Consumer Union from 2007 to December 2015 reveal that consumers often confuse the term natural with organic despite the fact that organic labeling of food is federally and state regulated.[2] Further, nearly half of consumers most recently surveyed incorrectly believed that natural claims had been independently verified. However, independent verification is required only by federal organic regulations.[3] And while "three-quarters of consumers perceived that organic food must be at least ninety-five percent free from synthetic additives, almost two-thirds expected the same of 'natural foods' " although there is no such regulation.[4] A majority of consumers (more than sixty-percent) also believed that "natural"

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[2]Andrea Rock, *Peeling Back the 'Natural' Food Label*, Consumer Reports, (Jan. 29, 2016), http://www.consumerreports.org/food-safety/peeling-back-the-natural-food-label/; *Food Labels Survey: 2015 Nationally-Representative Phone Survey*, CONSUMER REPORTS NATIONAL RESEARCH CENTER, http://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf.
[3]*Food Labels Survey: 2015 Nationally-Representative Phone Survey*, CONSUMER REPORTS NATIONAL RESEARCH CENTER, http://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf.
[4]*Consumer Insights on Organic and Natural,* NATURAL MARKETING INSTITUTE (Feb. 2015), http://organicandnatural.org/wp-content/content/uploads/2015/10/Consumer-Insights-onOrganic-and-Natural-A-Research-Study.pdf.

means that no amount of toxic pesticides, artificial ingredients, materials or colors, or chemicals were used during processing; and no GMO ingredients were used although in fact, many of these are not addressed by the current FDA advisory opinion.[5]

Finally, consumers' belief that natural foods are somehow better or healthier than conventional foods is demonstrated both by their willingness to pay more for the perceived benefits natural foods bestow and by manufacturers' growing use of the term. Sales of foods bearing natural labels topped $40 billion in 2013; that figure represents more than 10% of all food sales and more than twice the sales of organic food.[6]

Both Consumer Union consumer surveys and academic studies demonstrate that labeling a food "natural" creates a "health-halo" that overestimates the healthfulness of that particular food and that foods without a natural label do not enjoy. For example, a 2014 Harris Poll revealed that sixty-two percent of the surveyed consumers believed that packages advertising "natural," "all natural," or "100% natural," were helpful in directing them toward nutritious choices.[7] In a global consumer survey, respondents were requested to rate health attributes from very important to not important in their purchase decisions. The most desirable qualities chosen by consumers were foods that are fresh, natural and minimally processed. Foods that contained "all natural" ingredients and did not contain GMOs were considered very important to forty-three percent of the respondents, the highest percentages of the twenty-seven attributes included in the study.[8]

"Natural" Food Litigation Has Not Clarified the Meaning of "Natural"

The lack of any clear definition of "natural" has also resulted in litigation that has failed to resolve the confusion around the use of the term on food labels. The number of lawsuits challenging products labeled as "natural" has been steadily rising. In fact, since 2011 there have been more than one hundred putative class action lawsuits brought challenging the use of the term "natural" in food labeling.[9] These actions primarily allege deceptive and misleading labeling or advertising, or violations of state consumer protection laws.[10] Representative lawsuits typically fit into one of the following categories, food labeled as "natural" that: (1) contains artificial and/or synthetic ingredients;[11] (2) contains high fructose corn syrup;[12] (3) is

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[5] *Food Labels Survey: 2015 Nationally-Representative Phone Survey*, CONSUMER REPORTS NATIONAL RESEARCH CENTER, http://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf.

[6] Efthimios Parasidis, Neal Hooker, and Christopher T. Simons, *Addressing Consumer Confusion Surrounding "Natural" Food Claims*, 41 AM.J.L. & MED. 357, 365 (2015).

[7] Larry Shannon-Missal, *Guilt Free? Lite? Healthy? The Harris Poll Examines Consumer Confusion Over Grocery Labels*, The Harris Poll (Mar. 6, 2014, 12:00 AM), http://www.theharrispoll.com/health-and life/Guilt_Free__Lite__Healthy__The_Harris_Poll_Examines_Consumer_Confusion_Over_Grocery_Labels.html.

[8] *Nielsen Global Health and Wellness Report - We Are What We Eat: Healthy Eating Trends Around the World*, THE NIELSEN COMPANY (Jan. 2015), http://www.nielsen.com/content/dam/nielsenglobal/eu/nielseninsights/pdfs/Nielsen%20Global%20Health%20and%20Wellness%20Report%20-%20January%202015.pdf.

[9] PARASIDIS et al., *supra* note 6 at 367.

[10] *Id.*

[11] *See Musgrave v. ICC/Marie Callender's Gourmet Prods. Div.*, No. 3:14-cv-02006-HSG (N.D. Cal. filed May 1, 2014) (plaintiff alleged that defendant advertised a variety of bread and muffin mixes as "all natural" despite

processed with chemicals[13] and (4) contains GMOs.[14] While a number of courts have refused to dismiss plaintiffs' claims for deceptive practices and have held, based on the pleadings, that a reasonable consumer could have been misled by such claims, the bulk of these cases have not reached a final determination on the merits. Thus litigation has failed to shed light for either consumers or manufacturers as to what "natural" claims may be made.

The lack of clear regulatory guidance from FDA has left courts unsure of how, or even whether, to proceed, in actions challenging the use of "natural." Many courts have refused to stay actions challenging the use of the term "natural," specifically recognizing FDA's failure to act in this area. Others have ruled that such determinations should be left to the expertise of FDA.[15] The resulting inconsistencies do not aid in resolving these claims in a manner that furthers consumers' "interests in availability of information and a safe food supply, industry interests in predictability and narrowly tailored rules, and regulators' interests in uniformity and accuracy."[16] This further emphasizes the need for FDA to promulgate a federal definition of "natural."

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containing Sodium Acid Pyrophosphate ("SAPP"), a synthetic ingredient); *Barbara Anderson v. The Hain Celestial Grp., Inc. et al.*, No. 5:14-cv-03895-EJD (N.D. Cal. filed Aug. 28, 2014) (sunflower dream sunflower drink containing tricalcium phosphate, xantham gum, folic acid, vitamin A palmitate, and Vitamin D2); and *Klacko v. Diamond Foods, Inc.*, No. 9:14-cv-80005-BB (S.D. Fla. filed Jan. 3, 2014) (Kettle Brand products containing maltodextrin and/or dextrose).

[12] *See Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009) (pasta sauce containing high fructose corn syrup); Janney v. Mills, No. 12-cv-03919-WHO, 2014 U.S. Dist. LEXIS 41452 (N.D. Cal. March 26, 2014) (products made with high fructose corn syrup, high maltose corn syrup, and maltodextrin); and *Von Koenig v. Snapple Bev. Corp.*, 713 F. Supp. 2d 1066 (E.D. Cal. 2010) (products containing high fructose corn syrup).

[13] *See Angel Aguiar v. Merisant Co. et al.*, No. 2:14-cv-00670-RGK-AGR (C.D. Cal. Filed Jan. 28, 2014) (a "harshly chemically processed product"); and *Frohberg et al v. Cumberland Packing Corp.*, No. 1:14-cv-00748-RLM (E.D.N.Y filed Feb. 3, 2014) (manufacture of stevia products require multiple processing steps).

[14] *See Bevans v. Gen. Mills Inc.*, No. 2:12-cv-00249-KM-JBC (D.N.J. filed Jan. 13, 2012) (cereal containing genetically modified corn); *Trammell v. Barbara's Bakery Inc.*, No. 12-cv-02664-CRB (N.D. Cal. filed May 23, 2012) (products containing GMOs); *Garcia v. Kashi Co.*, 43 F. Supp. 3d 1359 (S.D. Fla. 2014)(products containing GMOs); *Ault v. J.M. Smucker Co., et. al.* No. 1:13-cv-03409-PAC, 2014 U.S. Dist. LEXIS 67118 (S.D.N.Y. May 21, 2013) (presence of genetically modified ingredients in Crisco products); and *In re Frito-Lay N. Am., Inc.*, No. 1:12-md-02413-RRM-RLM (E.D.N.Y. filed Dec. 12, 2012) (products containing GMOs).

[15] *See e.g. Dye v. Bodacious Food Co.*, No. 14-80627-CIV-DIMITROULEAS, 2014 U.S. Dist. LEXIS 180826, at *5 - *7 (S.D. Fla. Sept. 9, 2014) ("neither a dismissal nor a stay is warranted under the primary jurisdiction...The FDA is free to promulgate regulations governing the term 'natural' but has not done so."); *In re Frito-Lay N. Am., Inc.*, No. 12–MD–2413, 2013 U.S. Dist. LEXIS 123824, at *27-*29 (E.D.N.Y. Aug. 29, 2013) (refused to revoke primary jurisdiction and stay the action to request an opinion from the FDA concerning plaintiff's claims); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1035 (N.D. Cal. Feb. 3, 2009) (failing to invoke the doctrine here, finding "various parties have repeatedly asked the FDA to adopt formal rulemaking to define the word natural and the FDA has declined to do so because it is not a priority and the FDA has limited resources. Moreover, this is not a technical area in which the FDA has greater technical expertise than the courts—every day courts decide whether conduct is misleading."). *But see In re Gen. Mills Inc.*, No. 2:12-cv-00249-KM-JBC, 2013 U.S. Dist. LEXIS 160702 (D.N.J. Nov. 1, 2013) (The court invoking the doctrine of primary jurisdiction administratively terminated the case and referred to the FDA for an administrative determination); and *Cox v. Gruma Corp.*, No. 12-CV-6502 YGR, 2013 U.S. Dist. LEXIS 97207 (N.D. Cal. July 11, 2013) (the court stayed the case under the primary jurisdiction doctrine and referred the question to the FDA.).

[16] Diana R. H. Winters, *Inappropriate Referral: The Use of Primary Jurisdiction in Food-Labeling Litigation*, 41 AM.J.L. & MED. 240, 254 (2015).

Determining the Types of Food That Should be Allowed to Bear the Term "Natural"

FDA's current non-binding policy, published as an advisory opinion more than twenty years ago, describes "natural" to mean "nothing artificial or synthetic (including colors regardless of source) [was] included in, or has been added to, the product that would not normally be expected to be there."[17] The NYAG agrees that "nothing artificial or synthetic . . . that would not normally be expected to be there" should be part of any regulation, but also urges that the definition be expanded to address processing techniques and to ban the use of GMO ingredients. United States Department of Agriculture ("USDA") regulations regarding the labeling of meat and poultry products, are similar to FDA's in that USDA allows a food to be labeled as "natural" when it contains no artificial ingredients, no added color, no chemical preservatives, and is not more than minimally processed, that is, processed in a manner that does not fundamentally alter the food.[18] The NYAG agrees with both agencies' exclusion of ingredients that are artificial or synthetic, including chemical preservatives. The NYAG also recommends that an FDA definition adopt USDA's requirement that "natural" foods be minimally processed and for the reasons below, also exclude GMO ingredients.

Further, a determination of what foods may be allowed to bear the term "natural" should take into consideration where the ingredient or product falls on the continuum of what could be considered "natural" and how that compares to the consumer take-away of what a product labeled natural will or will not have in it. In other words, both science and consumer perception must be explored to ensure that consumers receive the perceived benefit of buying a product with the label "natural."

The Term "Natural" Should be Used Only with Respect to Food Processing Techniques That Involve Minimal Processing and Certain Food Safety Processing Techniques

A natural food in its unprocessed state is a raw agricultural commodity, that is, a fresh fruit, vegetable or grain. Generally, "natural" foods are not so highly processed that they no longer resemble the original food or lack the original chemical composition of the food.[19] However, many foods are processed for the safety or convenience of consumers and a number of these processes are accepted by consumers as not fundamentally altering a food's "natural" state. FDA has long grappled with attempts to define natural, none of which have resulted in formal

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[17] *See* FDA, Warning letter to Emilio Sandoval, Helados La Tapatia, Inc. (Oct. 24, 2014), available at, http://www.fda.gov/iceci/enforcementactions/warningletters/ucm421463.htm. (products may not bear "Natural" and "All Natural" labels because they contain chemical preservatives and other synthetic ingredients.)

[18] *Food Standards and Labeling Policy Book*, U.S. DEP'T AGRIC. FOOD SAFETY & INSPECTION SERV. (Aug. 2005). http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf. (Section specifically on Natural Claims). The NYAG does not recommend that FDA include USDA's requirement that "all products claiming to be natural or a natural food should be accompanied by a brief statement that explains what is meant by the term natural..." since adherence to an FDA definition of "natural" definition by the food industry would provide consumers with sufficient truthful information to make informed purchasing decisions.

[19] Connecticut GMO food labeling law (dormant unless bordering states enact similar legislation) defines natural as food that "has not been treated with preservatives, antibiotics, synthetic additives, artificial flavorings, or artificial coloring. Foods that have been "processed in a manner that makes such food significantly less nutritive" cannot be labeled natural. H.B. 6527, 2013 Gen. Assemb., Reg. Sess. (Conn. 2013).

regulations. Informal policies have struggled to remain relevant in light of ever-increasing industrialized agriculture, genetic modifications and sophisticated food processing.

Foods bearing the "natural" label should be no more than minimally processed, that is not so highly processed that it no longer resembles the original food or lacks the original chemical composition of the food. However, the NYAG understands this is an area open to many different levels of interpretation. Not surprisingly, minimal processing has several definitions that generally provide examples of those techniques that would be accepted by regulators and presumably consumers as minimal processing. For example, the Food Safety & Inspection Service ("FSIS"), USDA's public health agency responsible for ensuring meat, poultry and egg products are safe and correctly labeled and packaged defines minimal processing in its *Food Standards and Labeling Policy Book* as (1) 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 (2) 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.[20] Other processing techniques such as fermenting and adding natural preservatives to perishable foods are also considered minimal by scientists and nutritionists - and often necessary - since as a result of these processes the food retains most of its nutritional properties and remains edible for a longer period of time.[21]

Consumer focus groups conducted by the food industry supported International Food Information Council ("IFIC") provide insight into consumer perception involving food processing techniques and the type of processes that consumers consider minimal. Based on consumer responses, IFIC categorizes "minimally processed" foods to include foods such as washed and packaged fruit and vegetables; bagged salads; roasted and ground nuts and coffee. Consumers also consider foods that are "processed to help preserve and enhance nutrients and freshness of foods at their peak and includes canned and frozen foods" as minimally processed.[22]

Consumers also widely accept the pasteurization of milk products as a minimal process that is critical to protect public health. However, not all processes that make food safe to eat are considered minimal. Specifically, the FSIS does not permit the labeling of irradiated foods as "natural" because it considers the process to be more than minimal, nor can irradiated products be certified as organic.[23] Accordingly, consistent with existing standards, the NYAG recommends that an FDA definition of "natural" exclude irradiated food ingredients.

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[20] *Id.* at 18.

[21] *Food Processing Lesson Plan.* BLOOMBERG SCHOOL OF PUBLIC HEALTH, http://www.jhsph.edu/research/centers-and-institutes/teaching-the-food-system/curriculum/_pdf/Food_Processing-Lesson.pdf; MARION NESTLE, WHAT TO EAT 307 (2007).

[22] Processed foods: contributions to nutrition. Scientific Statement from the American Society for Nutrition. Am J Clin Nutr 2011;99: 1525-42. The committee considering the classification of foods opined that "a subjective definition based on the extent of processing is value-laden and does not characterize foods in a helpful manner."

[23] *Id.* at 18; *Irradiation Q's & A's*, U.S. DEP'T OF AGRIC. FOOD SAFETY AND INSPECTION SERV. (July 5, 2001), http://www.fsis.usda.gov/OPPDE/larc/Policies/Irradiation%20QA.pdf.

A Definition of "Natural" Should Exclude Genetically Modified Organisms ("GMOs")

The NYAG believes that foods developed with genetic modification techniques should be excluded from any proposed definition of "natural." This approach is similar to organic regulations which prohibit foods that contain genetically modified ingredients as being labeled organic. As confirmed by surveys and consistent with results in a number of court cases where courts found plaintiffs had stated a claim, consumers do not expect food labeled "all natural" to contain ingredients derived from GMO corn such as corn chips, corn oil, and high fructose corn syrup.[24]

Despite FDA pronouncements that genetically modified foods do not need to be labeled as such,[25] many consumers and federal and state lawmakers have long demanded such labeling. In November 2015, FDA acknowledged consumer interest "in knowing whether a food was produced using genetic engineering and some manufacturers want to respond to this consumer interest" and issued a Guidance permitting voluntary labeling of foods derived from GMOs as long as that information is truthful and not misleading.[26] Indeed, a recent national survey found that a whopping ninety-two percent of Americans believe that GMO foods should be labeled as such before they are sold.[27]

Consumer surveys also demonstrate high consumer demand for non-GMO products.[28] Awareness of consumer resistance to GMOs has led many companies to choose to use non-GMO ingredients in their products even though it requires reformulation and new ingredient sourcing. Some major global corporations, such as Campbell's Soup and Mars have now opted to voluntarily label their products if they contain genetically modified ingredients. Dannon has announced that it will remove GMO ingredients from its products and go a step further by sourcing milk from non-GMO fed cows by 2018.[29] Further, over sixty countries have mandatory

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[24] *Ault v. J.M. Smucker Co., et. al.* No. 1:13-cv-03409-PAC, 2014 U.S. Dist. LEXIS 67118 (S.D.N.Y. May 21, 2013) (it is not unreasonable that a consumer would believe non-organic foods labeled as "All Natural" do not contain GMOs); *In re Frito-Lay N. A.,* No. 12-MD-2413, 2013 U.S. Dist. LEXIS 123824 (E.D.N.Y. 2013) (holding that a "reasonable consumer viewing [Frito-Lay's] 'All Natural' labels could reach a variety of conclusions about their potential for containing genetically modified ingredients."); *Bevans v. Gen. Mills Inc.*, No. 2:12-cv-00249-KM-JBC (D.N.J. filed Jan. 13, 2012) (cereal containing genetically modified corn); *Trammell v. Barbara's Bakery Inc.*, No. 12-cv-02664-CRB (N.D. Cal. filed May 23, 2012) (products containing GMOs); *Garcia v. Kashi Co.*, 43 F. Supp. 3d 1359 (S.D. Fla. 2014) (products containing GMOs).

[25] FDA's decision not to require labeling of GMO foods was based on its determination that bioengineered foods do not differ from other foods in any "meaningful or uniform way" and that the development of new plant varieties including rDNA technology "is generally not material information" that would require disclosure on a food label. Statement of Policy: Foods Derived from New Plant Varieties 57 Fed. Reg. 22,984, 22,984-85 (May 29, 1992). FDA's determination that genetic engineering alone is not a material fact that warrants food labeling withstood a court challenge. *See, Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 178–79 (D.D.C. 2000).

[26] *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants*, U.S. FOOD AND. DRUG ADMIN. (Nov. 2015), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm059098.htm.

[27] *GMO Foods: What You Need To Know*, CONSUMER REPORTS MAGAZINE (Feb. 26, 2015), http://www.consumerreports.org/cro/magazine/2015/02/gmo-foods-what-you-need-to-know/index.htm.

[28] *Id.*

[29] *Dannon Announces Breakthrough Sweeping Commitment for Sustainable Agriculture, More Natural Ingredients and Greater Transparency*, DANNON (Apr. 27, 2016), http://www.dannon.com/the-dannon-pledge-on-sustainable-agriculture-naturality-and-transparency/.

labeling for foods that contain genetically modified ingredients and states, such as Vermont, have passed mandatory labeling laws for GMO products.

FDA should now also recognize that consumers do not consider foods containing GMO ingredients to be "natural" and exclude them from any definition of the term.

Defining "Natural" Will Have Public Health and Nutritional Benefits

Surveys consistently demonstrate that consumers bestow health benefits on foods with natural labels including highly processed foods that claim to be "all natural" or that contain "natural" ingredients.[30] Yet processed food ingredients are often "nutrient-poor," that is, they are high in calories relative to the amount of vitamins, minerals and other important dietary nutrients they contain.[31] If the definition of "natural" excludes foods that are more than minimally processed, this should result in public health and nutritional benefits.

Although the benefits of minimally processed foods are clear, the American diet is heavily dependent on processed foods. A food industry supported analysis of the nutrient contribution of processed foods in the American diet based on thirty years of government food intake surveys ("The National Health and Nutrition Examination Survey or "NHANES"), revealed that minimally processed foods (as defined by consumer focus groups) accounted for only approximately 300 calories yet provided more than 20% of dietary fiber, vitamin D, calcium, potassium and vitamin B-12 in the American diet. Also, minimally processed foods when compared with their energy (calorie) contribution provided a higher percentage of dietary fiber, vitamin D, calcium, potassium and vitamin B-12 to the diet and a lower percentage of sodium and added sugars to American diets than processed foods.[32] In contrast, processed foods provided approximately 1200 calories and the majority of saturated fat, sodium, and added sugars. They also provided a higher percentage of iron and folate and other nutrients, however, many of these nutrients are added as enrichment (replacing nutrients lost in processing) or fortification (adding nutrients at higher amounts than naturally occur in the food) after processing.[33]

If the federal definition of "natural" provides that only minimally processed foods may carry that label, then the nutritional profile of "all natural" foods will reflect a more healthful nutrient content and contain less of those ingredients that the Dietary Guidelines urge consumers to avoid. As the demand for natural foods continues to grow, consumers who choose natural foods will be eating more healthfully. Conversely, less healthful foods that have been

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[30] Amber Walters & Marilee Long, *The Effect of Food Label Cues on Perceptions of Quality and Purchase Intentions Among High-Involvement Consumers with Varying Levels of Nutrition Knowledge*, 44 J. NUTRITION EDUC. & BEHAV. 350, 350-351 (2010).

[31] Carlos Augusto Monteiro et al., *A New Classification Of Foods Based On The Extent And Purpose Of Their Processing*, 26(11) Cad. Saude Publica 2039, 2040 (2010).

[32] Connie M. Weaver et al., *Processed Foods: Contribution To Nutrition*, 99 THE AM. J. CLIN. NUTR. 1525, 1530 (2014).

[33] Although minimal processing most often results in natural foods retaining more nutrients that provide nutritional benefits to consumers, we do not recommend there be a threshold level of vitamins, minerals or other nutrients for a food to be labeled natural.

deceptively labeled as "natural" will no longer be allowed to do so. This, too, ultimately benefits the public health.

Recommended FDA Actions to Ensure That Consumers Have a Consistent and Accurate Understanding of the Term "Natural" in Food Labeling

A consistent definition of "natural" combined with a public education campaign that introduces the term "natural" as defined by FDA would greatly assist consumers in understanding its use on a label or in advertising.

Current consumer confusion stems in large part from the inconsistent and misleading use of "natural" and the lack of enforcement action by FDA. Consistent and accurate labeling of products in the marketplace in accordance with a definition that provides adequate guidance will help inform consumers' understanding of the term "natural." A public educational campaign should be undertaken to complement this process. For example, nationwide educational initiatives such as "Read the Label" encourage children and parents to make smarter food choices with tips on reading labels, as well as providing community outreach manuals and presentations that can be used at afterschool events and community education organizations.[34] The Bloomberg School of Public Health has created a curriculum designed to teach students the differences between minimally processed foods, food ingredients and highly processed foods, in simple, non-technical language.[35] Agricultural extension colleges have also created teaching tools to explain food processing and its nutritional impact.[36] There is a wealth of information currently available which FDA can incorporate into its own educational and outreach materials.

Enforcement of regulations and consumer laws by federal and state officials is also integral to consumers' understanding of what the term "natural" represents on a food label.

How Should the FDA determine Whether Foods Labeled "Natural" Comply with Applicable Criteria?

FDA already possesses the tools necessary to determine whether foods labeled natural are truthful and not misleading. For example, FDA has, on occasion, enforced its current "natural" policy using Warning Letters, for example, when a frozen processed potato product claimed on its label to be "all natural" yet contained a synthetic chemical preservative. The FDA also noted in the same letter that several of this brand's products carried an "All Natural" statement on the label and recommended that the company review all of its product labels to avoid additional instances of misbranding.[37] The analysis employed by FDA in the warning label process as well as other enforcement practices at its disposal to challenge food claims that are misleading and/or result in foods being misbranded would be equally applicable to misleading "natural" claims.

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[34] Nutrition Facts Label: Read the Label Youth Outreach Campaign, U.S. FOOD AND DRUG ADMIN. (last updated Mar. 14, 2016), http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm281746.htm.

[35] *Food Processing Lesson Plan*, BLOOMBERG SCHOOL OF PUBLIC HEALTH. http://www.jhsph.edu/research/centers-and-institutes/teaching-the-food-system/curriculum/_pdf/Food_Processing-Lesson.pdf.

[36] *The Quicker The Better? Food Processing*, NATIONAL AGRICULTURE IN THE CLASSROOM, https://www.agclassroom.org/teacher/matrix/lessonplan.cfm?lpid=402.

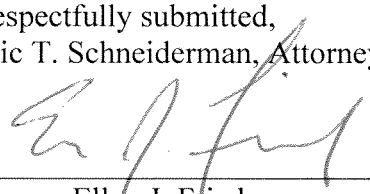
[37] See FDA, Warning letter to Alex Dzieduszycki, Alexia Foods (Nov. 16, 2011), available at, http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm281118.htm.

Any "Natural" Regulation by FDA Should Not Preempt State Law

State consumer protection statutes provide state Attorneys General with the statutory authority to protect consumers from deceptive practices. The NYAG has used this authority on multiple occasions to protect consumers from false and misleading marketing and advertising of food products.[38] Whether a claim that a food label such as "natural" is misleading under state consumer laws is one that courts are well-equipped to handle.[39] Indeed, courts have consistently held that FDA's current "natural" policy does not preempt state consumer protection laws prohibiting false and misleading advertising and deceptive business practices.[40] State law remedies, including monetary relief and monitoring of company adherence to food labeling laws, also provide consumers with additional protection from misleading and deceptive marketing of food products.

In conclusion, we commend FDA for renewing its efforts to define the term "natural." A federal definition will provide consumers with the information they need to make informed and healthful nutritional decisions about the foods they and their children eat. It will provide the food industry with the information it needs to promote products in a truthful and non-deceptive manner. And, it will also provide federal and state law enforcement officials with clear guidance to ensure that the marketplace remains free from misleading and deceptive natural labels, save litigation costs and court resources, and reward those who truthfully label food products. If we can provide any further information or assistance related to FDA's request regarding the use of term "natural" in the labeling of human food products please do not hesitate to contact us.

Respectfully submitted,
Eric T. Schneiderman, Attorney General



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[38] *See e.g.* Marian Burros, Eating Well; Food Companies Agree to Modify Claims on Fat, NEW YORK TIMES, Oct. 30, 1991, at C1 (Nestle', KFC and Dunkin' Donut cease misleading low fat and cholesterol claims related to particular products); and Carole Sugarman, States Question National Promotions: Ad Regulations Have Companies in a Pickle, LOS ANGELES TIMES, Oct. 13, 1988, at 41 (Kellogg Co. ceases misleading claims regarding Rice Krispies and Vitamin B); Agreement Clarifies Labeling of Fruit Juices, http://www.ag.ny.gov/press-release/agreement-clarifies-labeling-fruit-juices, Aug. 1, 2000. (Mott revises misleading labels regarding fruit content of juices).

[39] *See* Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA As A Failed Statute*, 89 TUL. L. REV. 815 (2015).

[40] *See e.g. Astiana v. Ben & Jerry's Homeade, Inc.*, No. 4:10-cv-04387-PJH, 2011 U.S. Dist. LEXIS 57348 (N.D. Cal. May 26, 2011); *Musgrave v. ICC/Marie Callender's Gourmet Prods. Div.*, No 3:14-cv-02006-HSG , (N.D. Cal. filed May 1, 2014);. *Ault v. J.M. Smucker Co., et al.*, No. 1:13-cv-03409-PAC, 2014 U.S. Dist. LEXIS 67118 (S.D.N.Y. May 21, 2013); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009); *Astiana v. Hain Celestial Grp., Inc.,* 783 F.3d 753 (9th Cir. 2015); and *Garrison v. Whole Foods Mkt. Grp. Inc.*, No. 13-cv-05222-VC, 2014 U.S. Dist. LEXIS 75271 (N.D. Cal. 2014).