May 10, 2016

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

Re: Docket No. FDA–2014–N–1207

Comments to FDA on Use of the Term "Natural" in the Labeling of Human Food Products

To the United States Food and Drug Administration (FDA):

The Center for Food Safety (CFS) submits the following comments on behalf of itself and its members in response to FDA's Request for Information and Comments regarding Use of the Term "Natural" in the Labeling of Human Food Products, 80 Fed. Reg. 69,905 (Nov. 12, 2015). In addition, CFS's comments are joined by the Center for Biological Diversity and Friends of the Earth.

Introduction and Summary

CFS is a nonprofit, public interest advocacy organization dedicated to protecting human health and the environment by curbing the proliferation of harmful food production technologies and promoting sustainable agriculture. CFS is dedicated to protecting and furthering the public's right to know how their food is produced through accurate labeling and other means. As a membership organization, CFS represents over 750,000 farmer and consumer members who reside in every state across the country, and who support safe, sustainable food systems.

The Center for Biological Diversity (CBD) is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. CBD has more than one million members and online activists dedicated to the protection and restoration of endangered species and wild places. CBD has worked for twenty-six years to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. CBD is committed to protecting the environmental and public health, including by engaging in matters regarding the appropriate and non-deceptive use of human food labels.

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Friends of the Earth is the U.S. voice of the world's largest network of grassroots environmental organizations, with groups in seventy-four countries. For more than forty-five years, Friends of the Earth, along with our nearly 600,000 online supporters and members, has worked at the nexus of environmental protection, economic policy, and social justice to fundamentally transform the way our country and the world value people and the environment. It is in this light that Friends of the Earth has been following the development of genetic engineering, raising awareness about the environmental and health risks, and the need for more robust government oversight and assessment related to genetically engineered organisms.

The term "natural" as currently used on food labels is inherently misleading. Many consumers equate the term "natural" with "organic" or value "natural" products more highly than "organic" products, despite the fact that while products bearing the "organic" label are subject to rigorous standards and third-party verification requirements, the term "natural" lacks a legally binding definition and enforceable standards. Corporations have been profiting from consumers' confusion, marketing their products as "natural" and enticing consumers with the notion that their products meet certain criteria, such as being free from genetically engineered (GE) ingredients and pesticides, when in fact these products are not required to comply with any such standards. Because misuse of the term "natural" has permeated the marketplace to such a great extent and has been corrupted beyond the point of rehabilitation, CFS and its members believe FDA should prohibit using the term "natural" on human food labels.

If FDA decides to define the term "natural" as used on human food labels, it should do so through the notice-and-comment rulemaking process, as required by the Administrative Procedure Act, in order to promote public participation and transparency of agency processes, as well as provide clarification and legal protection for consumers. If FDA allows use of the term "natural," the term should only encompass single-ingredient foods, which would protect consumers from additional misperceptions by coinciding with a broad base of consumer expectations. In addition, if FDA promulgates a definition of "natural," the Agency should explicitly exclude foods produced in whole or in part with genetic engineering (GE) because allowing GE foods to be labelled as "natural" would be exceptionally misleading to consumers.

FDA Should Prohibit the Term "Natural" on Labels for Human Food Products

History of Natural Labeling

This is not the first time FDA has solicited comments concerning whether and how to define the term "natural" as used on food labels. In 1991, FDA solicited comments on a potential rule adopting a definition for the term "natural," noting that the use of "natural" on food labels "[is] of considerable interest to consumers and industry."[1] Two years later, however, FDA declined to define "natural," concluding that while "the ambiguity surrounding the use of this term . . . could be abated" if the term were adequately defined, the Agency would have to

[1] *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60,421, 60,466 (proposed Nov. 27, 1991) (to be codified at 21 C.F.R. pts. 5, 101, and 105).

carefully consider many facets of the issue if it undertook such a rulemaking, which it was unwilling to do because of "resource limitations and other agency priorities."[2]

On January 6, 1993, FDA issued a guidance document to address "natural" labeling. The guidance stated that FDA would "maintain its current policy . . . not to restrict the use of the term 'natural' except for added color, synthetic substances, and flavors," and that it would "maintain its policy regarding the use of 'natural,' as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food."[3] When questions over the use of "natural" arise, as they regularly do, FDA occasionally refers to these statements. However, the Agency has yet to formally issue a definition of "natural" and has not issued a final rule to address it.

In 2002, a nonprofit organization asked FDA to take action against an ice cream producer that labeled its products "all natural." FDA's response was that defining "natural" was "not among the FDA's current enforcement priorities." Then in 2006, the Sugar Association petitioned FDA to define "natural," and FDA likewise declined to do so. Another petition sent in 2007 by Sara Lee Corporation, a leader in the U.S. market for baked goods, claimed that a formal definition of "natural" would provide consistency for consumers and manufacturers alike. While FDA has not formally responded to the petitions, a top-ranking FDA official was quoted as saying defining natural was not a priority because the Agency was "not sure how high of an issue it is for consumers."

In 2010, a number of U.S. District Courts issued six-month stays of pending litigation over the use of "natural" on beverages containing high-fructose corn syrup (HFCS), in the hopes that FDA would formally define "natural." For example, on June 15, 2010, Judge Simandle of the United States District Court for the District of New Jersey referred to FDA for administrative determination, the question of whether HFCS qualifies as a "natural" ingredient.[4] Once again, FDA declined to do so.[5] The tide of litigation concerning "natural" product labels has not ebbed in the years leading up to FDA's present call for comments.[6]

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[2] *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993) (to be codified at 21 C.F.R. pts. 5 and 101).
[3] *Id.* (internal citation omitted).
[4] *Coyle v. Hornell Brewing Co.,* Civil No. 08-02797 (JBS), 2010 WL 2539386, at *1 (D.N.J. June 15, 2010).
[5] *See* Order Lifting Stay, *Coyle v. Hornell Brewing Co.*, Civil No. 08-02797 (JBS) (D.N.J. Sept. 23, 2010), ECF No. 119.
[6] *See, e.g., Garrison v. Whole Foods Market Grp., Inc.*, Case No. 13–cv–05222–VC, 2014 WL 2451290 (N.D. Cal., June 2, 2014) (granting in part and denying in part defendant motion to dismiss class action alleging several Whole Foods products were misleadingly labeled "all natural" because they contained synthetic ingredients); *Marshall v. Monster Beverage Corp*., Case No. 14–cv–02203–JD, 2014 WL 3870290 (N.D. Cal. Aug. 6, 2014) (litigation alleging defendant company engaged in deceptive labeling and advertising by claiming beverage products are "natural").

The Term "Natural" Is Misleading to Consumers

The prevalence of litigation surrounding the "natural" label on food products stems from the rampant confusion among consumers concerning the term's meaning and standards—or rather, the lack thereof. A myriad of research indicates many consumers have specific expectations for "natural" food products they purchase. For instance, sixty percent of consumers believe that a "natural" label on packaged and processed foods indicates the product is free from genetically engineered ingredients, and over sixty percent believe "natural" food products do not contain pesticides, chemicals, artificial materials or ingredients, or artificial coloring.[7] In addition, nearly half of consumers believe that products labeled as "natural" are subject to third-party verification, even though no such regulation of the label exists and the term, as applied to food products, is "essentially meaningless."[8] However, this label helps the food industry sell nearly $41 billion worth of food products each year.[9]

More specifically, consumers confuse products that are labelled "natural" with those labelled as "organic." One third of consumers do not think there is any difference between these two labels.[10] In addition, nearly as many consumers believe the term "natural" is governmentally regulated as believe the term "organic" is regulated.[11] An even more troubling issue is that many consumers actually view "natural" products as superior to "organic," unduly elevating the unregulated term's status in the marketplace. For example, only fourteen percent of consumers regard "100% organic" as the most desirable "eco-friendly" product label claim, while over thirty percent consider "100% natural" to be the best "eco-friendly" product label.[12] Consumers are also more likely to purchase foods labelled as "natural" than those labelled as "organic"—one survey shows sixty-two percent of consumers use "natural" food products at least once a week, while only thirty-nine percent of consumers use "organic" food products at least once a week.[13]

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[7] Consumer Reports Nat'l Research Ctr., *Natural Food Labels Survey: 2015 Nationally-Representative Phone Survey* 6 (2015), *available at* https://www.consumerreports.org/content/dam/cro/magazine-articles/2016/March/Consumer_Reports_Natural_Food_Labels_Survey_2015.pdf.

[8] *Id.* at 4, 8.

[9] Roberto A. Ferdman, *The word "natural" helps sell $40 billion worth of food in the U.S. every year—and the label means nothing*, Wash. Post (June 24, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/06/24/the-word-natural-helps-sell-40-billion-worth-of-food-in-the-u-s-every-year-and-the-label-means-nothing/.

[10] Organic & Natural Health Ass'n, *Consumer Insights on Organic and Natural: A Research Study Prepared by Natural Marketing Institute* 3 (2015), *available at* http://organicandnatural.org/wp-content/uploads/2015/10/Consumer-Insights-on-Organic-and-Natural-A-Research-Study.pdf.

[11] *Id*.

[12] Cornucopia Inst., *Cereal Crimes: How "Natural" Claims Deceive Consumers and Undermine the Organic Label—A Look Down the Cereal and Granola Aisle* 10 (2011), *available at* http://cornucopia.org/cereal-scorecard/docs/Cornucopia_Cereal_Report.pdf.

[13] Organic & Natural Health Ass'n, *supra* note 10, at 4.

This conflation of the terms "natural" and "organic" from the consumer's perspective is particularly problematic in light of the fact that in order to bear the "organic" label, producers and handlers of these products must comply with strict standards set forth in the Organic Foods Production Act (OFPA) and its implementing regulations through the National Organic Program, while "natural" products are not subject to any comparable requirements.[14] For instance, under OFPA, products bearing the "organic" label must be "produced and handled without the use of synthetic chemicals, except as otherwise provided [by OFPA]"; must "not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest" of the products; and must be produced in accordance with an organic production plan.[15] OFPA's implementing regulations include an extensive list of synthetic substances specifically prohibited from organic products.[16] In addition, these regulations bar the use of genetic engineering for organic products.[17] Facilities producing or handling organic products must also undergo inspection by a third-party certifying agent accredited by the United States Department of Agriculture (USDA).[18] Thus, products labeled as "organic" are subject to consistent, transparent, and legally-enforceable standards.

In stark contrast, the "natural" label is not subject to third-party verification and is not measured against a uniform standard, leaving individual companies to devise their own "natural" criteria (if any) that they can change without notifying consumers. As a result, the "natural" label does not effectively convey any useful information to consumers about the production methods or ingredients used for these products. Rather, many food product companies and marketers have harnessed the widespread consumer appeal and attendant inaccurate beliefs concerning the "natural" label, using them to their advantage to entice customers and drive product sales. Companies and marketers have taken advantage of consumers' willingness to pay a premium for products they perceive as meeting particular benchmarks, such as being free from pesticides, GE ingredients, and harmful chemicals, by raising the prices of "natural" products closer to, and even above in some cases, the prices of equivalent organic products, without having to expend the funds necessary to comply with the rigorous standards for organic products.[19]

However, defining the term "natural" in a way that adopts the same standards as required by OFPA and the National Organic Program would simply continue and even exacerbate consumer confusion. Furthermore, defining "natural" as comprising many of the same criteria as those outlined by the National Organic Program would be duplicative; unnecessarily divert finite agency resources to ensure public participation in, compliance with, and enforcement of the overlapping standards; and could lead to regulatory conflicts between FDA and USDA. Rather than implementing a superfluous regulatory framework that will duplicate the organic standards,

[14] *See* 7 U.S.C. § 6504; 7 C.F.R. §§205.100-.499.
[15] 7 U.S.C. § 6504; *see also* 7 C.F.R. § 205.102.
[16] *See* 7 C.F.R. §§ 205.600-.606.
[17] *Id.* §§ 205.105, 205.2 (defining "excluded methods" that "are not considered compatible with organic production" as including "cell fusion microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology).").
[18] *Id*. §§ 205.400(c); 205.403; 205.2.
[19] Cornucopia Inst., *supra* note 12, at 18-20.

FDA should guide consumers seeking foods free from pesticides, synthetic substances, and genetically engineered ingredients to the National Organic Program and associated organic label. Because the confusion enveloping the "natural" label has accumulated and calcified to the point where it cannot be cleared away, and because it would be nearly impossible to disentangle the term "natural" from the organic standards, the term "natural" has been stripped of any useful purpose and serves only to confuse consumers. As a result, CFS and its members support prohibiting use of the term "natural" on human food labels.

Prohibiting Use of the Term "Natural" Furthers the Free Speech Principles of the First Amendment

The First Amendment's protection of free speech does not extend to speech that is "more likely to deceive the public than to inform it," meaning the government may prohibit speech that is "actually or inherently misleading."[20] Indeed, "where the particular advertising is inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive . . . [the] [m]isleading advertising may be prohibited entirely."[21] As a result, courts have upheld government proscriptions of terms in advertisements that are "inherently misleading and, therefore, beyond First Amendment protection."[22] Moreover, such marketing terms have been deemed "likely to deceive and . . . therefore inherently misleading" when the terms "ha[ve] no fixed meaning" in the marketplace, their definitions "var[y] over time and from" advertiser to advertiser, and they "convey[] no useful information to the consumer."[23]

Thus, FDA can prohibit natural labeling if it finds such labeling to be either actually misleading or inherently misleading. Both apply here. First, the public record shows that consumers are actively being misled by natural labeling. Market research consistently indicates that consumers have been misled by the use of the term "natural" on food labels. Food products labelled as "natural" can, and often do, contain synthetic materials and chemicals, genetically engineered ingredients, and ingredients treated with pesticides.[24] This flies in the face of

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[20] *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 563 (1980) (citation omitted); *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 111 (1990) (Marshall, J., concurring).

[21] *In re R.M.J.*, 455 U.S. 191, 202-03 (1982).

[22] *See, e.g., Joe Conte Toyota, Inc. v. La. Motor Vehicle Comm'n*, 24 F.3d 754, 754 (5th Cir. 1994) (upholding state regulation banning use of the term "invoice" in motor vehicle advertisements).

[23] *Id.* at 756-57 (citation omitted).

[24] *See, e.g.*, Complaint at ¶3, *Bates v. Kashi Co.*, Case No. 11-cv-1967H BGS (S.D. Cal. Aug. 24, 2011) ("Kashi's so-called 'All Natural' GoLean Shakes are composed almost entirely of synthetic and unnaturally processed ingredients, including sodium molybdate, phytonadione, sodium selenite, magnesium phosphate, niacinamide, calcium carbonate, calcium phosphate, calcium panthothenate, pyridoxine hydrochloride, thiamin hydrochloride, potassium iodide, and other substances that have been declared to be synthetic substances by federal regulations."); Cornucopia Inst., *supra* note 12, at 9 (giving examples of companies that have released their policies concerning their "natural" product labels that have not excluded "synthetic and toxic

consumer expectations, as the majority of consumers presume that the "natural" food products they purchase are free from pesticides, chemicals, artificial ingredients, and genetically engineered ingredients.[25] Because evidence indicates the "natural" label is "a particular form or method of advertising that has in fact been deceptive, th[is] advertising enjoys no First Amendment protection."[26]

Second, the term "natural" as used on food product labels is also inherently misleading. Commercial speech is inherently misleading when it is "inherently likely to deceive the public" or when the speech is "devoid of intrinsic meaning."[27] Labeling products as "natural" plays upon consumer expectations while failing to convey any concrete, useful information. The term "natural" also "has no fixed meaning," its definition shifting over time and from company to company, as evidenced by food manufacturers who have released differing individual policies concerning their use of the term.[28] Consequently, the term "natural" is "inherently misleading" to consumers "and, therefore, beyond First Amendment protection."[29] Because "[t]he government may ban forms of communication more likely to deceive the public than to inform it," FDA should exercise this power to protect consumers and prohibit the use of "natural" on human food labels.[30]

If FDA Chooses to Define the Term "Natural," the Agency Should Do So in a Way That Promotes Public Participation and Minimizes Consumer Confusion

Because the term "natural" on food labels has been corrupted to such an extent that it cannot be rehabilitated to serve a useful purpose, CFS and its members support prohibiting use of the term "natural" on human food labels in order to quell consumer confusion, curb corporate misinformation, and prevent dilution of the organic standards. However, if FDA chooses to define the term "natural," it should follow the formal rulemaking process utilizing public notice-and-comment procedures in order to foster agency transparency. Furthermore, if FDA chooses to define "natural," FDA's definition should only include single-ingredient foods and should explicitly exclude foods produced with genetic engineering and other inherently unnatural food technologies, in order to prevent misleading consumers.

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pesticides, herbicides and fumigants," as well as genetically engineered ingredients, from their policies).

[25] Consumer Reports Nat'l Research Ctr., *supra* note 7, at 6.

[26] *Am. Acad. of Pain Mgmt. v. Joseph*, 353 F.3d 1099, 1107 (9th Cir. 2004) (citation and internal quotation marks omitted).

[27] *Joe Conte Toyota, Inc.*, 24 F.3d at 756 (citations omitted).

[28] *See id.* at 756-57; Cornucopia Inst., *supra* note 12, at 9 (describing the "natural" policies of Hain Celestial Group and Weetabix/Barbara's Bakery).

[29] *Joe Conte Toyota, Inc.*, 24 F.3d at 754.

[30] *See Central Hudson*, 447 U.S. at 563.

If FDA Defines the Term "Natural," It Should Define the Term Through the Administrative Rulemaking Process

If FDA decides to move forward with defining the term "natural" as used on the labeling of human food products, CFS and its members urge FDA to define the term through the rulemaking process provided by the Administrative Procedure Act (APA), as opposed to simply revising the Agency's policy on the term natural outlined in a 1993 FDA guidance document, or in some other *ad hoc* manner.[31] In contrast to FDA unilaterally revising its guidance policy concerning the term "natural," carrying out the APA rulemaking process will enable robust public participation and ensure a transparent and accountable agency process. Public participation is especially critical when defining the term "natural" in light of the general public's confusion surrounding the term—engaging the public and incorporating consumer input will ensure the definition conforms to consumer expectations.

The APA requires that agencies provide notice of proposed rulemaking and an opportunity for the public to comment.

> In enacting the APA, Congress made a judgment that notions of fairness and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment. . . . It is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later.[32]

Agency regulations do not have the force of law until they have gone through this process and are finalized "pursuant to the statutory procedural minimum" required by the APA.[33] Therefore, FDA's current guidance concerning use of the term "natural" on food labels does not provide the same level of legal protection for consumers that an enforceable, final rule promulgated through notice-and-comment rulemaking would provide.

In its initial proposal to define natural in 1991, FDA recognized its duty under the APA and provided the public with notice and an opportunity to comment. FDA itself has acknowledged that defining "natural," without engaging in notice-and-comment rulemaking, would be contrary to the principles of transparency and public participation to which the Agency is committed. For example, in its response to a previous request by a court to define natural, FDA explained that it would be inappropriate to respond to the court's question in this manner without participation of the public:

> [In order to] resolve whether HFCS qualifies as a "natural" ingredient in defendants' beverages, in the absence of a pre-existing regulatory definition, the

[31] *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. at 2407.
[32] *Paulsen v. Daniels*, 413 F.3d 999, 1004-05 (9th Cir. 2005) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 316 (1979)).
[33] *Chrysler Corp.*, 441 U.S. at 313.

> agency would expect to act in a transparent manner by engaging in a public proceeding to establish the meaning of this term. Given the issues involved, making such a determination without adequate public participation would raise questions about the fairness of FDA's action.[34]

Here, if FDA endeavors to define "natural," it should adhere to the requirements of the APA, to FDA's longstanding position on transparency, and to its own past practice by allowing consumers and other stakeholders an opportunity to comment on such an important matter of public health and consumer protection.

If FDA Defines the Term "Natural," the Definition Should Only Include Single-Ingredient Foods

If FDA opts to define "natural" as used on human food labels, FDA should confine the meaning of the term "natural" to single-ingredient foods, such as bottled water and bagged spinach. Limiting use of the "natural" label to single-ingredient foods offers several advantages. For instance, single-ingredient foods correspond to the commonsense, dictionary definition of "natural," which is "existing in nature," "not having any extra substances or chemicals added," and "not containing anything artificial."[35] Defining "natural" as including only single-ingredient foods would avoid misleading consumers because it fits a wide spectrum of consumer expectations by ruling out foods containing a variety of synthetic and chemical-based ingredients. Assigning the term "natural" a meaning that is sufficiently distinct from "organic" will also curtail consumer confusion concerning the two terms, preventing food companies from further benefiting from consumer misunderstandings about the terms and avoiding additional dilution of the organic standards.[36]

If FDA Defines the Term "Natural," the Definition Should Exclude GE Foods

In addition, if FDA determines it will define the term "natural," the definition should exclude foods produced in whole or in part with genetic engineering. Labeling GE foods with the word "natural" is exceptionally misleading to consumers. Most consumers, if asked, would *not* consider GE foods as natural, under the generally recognized meaning of the term. Black's Law Dictionary defines "natural" as something that is "[i]n accord with the regular course of things in the universe and without accidental or purposeful interference" or "[b]rought about by nature as opposed to artificial means."[37] Foods that have been genetically engineered do not fit within either of these, or the previously discussed, definitions of "natural."

Genetic engineering, in contrast to "natural" processes, usually involves the insertion of foreign (often bacterial) genetic material into cells or tissues of a food plant or crop. These cells or tissues are kept artificially alive in a laboratory, and are then manipulated to form viable

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[34] Order Lifting Stay, *Coyle v. Hornell Brewing Co.*, Civil No. 08-02797 (JBS) (D.N.J. Sept. 23, 2010), ECF No. 119.
[35] *Natural*, Merriam-Webster, http://www.merriam-webster.com/dictionary/natural (last visited Apr. 27, 2016).
[36] *See* Cornucopia Inst., *supra* note 12, at 11-13.
[37] *Natural*, BLACK'S LAW DICTIONARY (10th ed. 2014).

plants that are selected for expression of the laboratory-introduced trait. Gene insertion occurs by artificial means—through a gene "gun," a bacterial vector, or chemical or electrical treatment—without regard for natural species boundaries. Biotechnicians may use DNA sequences known as promoters derived from genetic parasites, such as viruses, that have been designed to breach species barriers, in order to ensure that the desired amount of the introduced gene product will be made at the desired time. Neither vectors nor promoters are needed in traditional breeding.[38]

Scientists may even insert custom-designed genes that have no counterpart in nature.[39] One FDA expert summed up the novel nature of these foods: "We should also keep in mind that plant genetic engineering is an *entirely new* adventure with potentially new effects."[40]

As the name itself also affirms, there is nothing "natural" about *genetically engineered* organisms. Review of the Monsanto Company's definition of genetically modified organisms (GMOs) confirms their decidedly *un*natural nature. It defines GMOs as "any organism the genetics of which have been altered through the use of modern biotechnology to create a novel combination of genetic material."[41] The World Health Organization defines genetically engineered organisms as "organisms . . . in which the genetic material (DNA) has been altered in a way that *does not occur naturally*. . . ."[42] Thus, genetic engineering is explicitly defined as an unnatural process (i.e. unnatural alteration of DNA) that results in the creation of an unnatural organism, and as a result, labeling GE foods as "natural" is misleading to consumers.

i. <u>The Technology Used to Produce GE Foods Implicates Significant Food Safety Concerns</u>

Not only are GE foods unnatural, they are the products of a radical new technology that raises greater food safety concerns than time-tested traditional breeding practices. According to

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[38] Michael K. Hansen, Consumer Policy Inst./Consumers Union, *Genetic Engineering is Not an Extension of Conventional Plant Breeding: How Genetic Engineering Differs From Conventional Breeding, Hybridization, Wide Crosses and Horizontal Gene Transfer*, 1, 7 (2000), *available at* http://consumersunion.org/wp-content/uploads/2013/02/Wide-Crosses.pdf. The cauliflower mosaic virus promoter (CaMV 35S) is used because it leads to hyperexpression of the foreign gene to which it is linked. The CaMV 35S promoter effectively puts the transgene(s) outside of virtually any regulatory control by the recipient plant. *Id.*

[39] *Id.* at 1.

[40] U.S. Food & Drug Admin., Comments on proposed approach to unknown and unexpected toxicants (undated) (on file with author) (emphasis added).

[41] Monsanto, *Glossary*, http://www.monsanto.com/newsviews/Pages/glossary.aspx#gmo (last visited May 9, 2016). Monsanto has also previously defined GMOs as "[p]lants or animals that have had their genetic makeup altered to exhibit traits that are *not naturally theirs*. In general, genes are taken (copied) from one organism that shows a desired trait and transferred into the genetic code of another organism." *Id.* (last visited Oct. 29, 2013) (emphasis added).

[42] World Health Org. (WHO), *Frequently asked questions on genetically modified foods*, http://www.who.int/foodsafety/areas_work/food-technology/faq-genetically-modified-food/en/ (last visited May 9, 2016) (emphasis added).

FDA scientist Linda Kahl, "[t]he processes of [GE] and traditional breeding are different, and. . . they lead to different risks."[43]

Because GE foods lack traditional foods' centuries-long history of safe use, scientific testing is needed to assess them. The most widely discussed risk is food allergies.[44] Most GE foods are engineered to contain novel transgenic proteins, frequently derived from bacteria, that either have never been part of the human diet, or are new to the food in question. Such novel transgenic proteins can induce food allergies. Allergic reactions range in severity from mild respiratory distress to life-threatening anaphylactic shock. The number of allergy-related episodes in the U.S. doubled from 1997 to 2002, when GE crops were being introduced. Food allergies, which account for more than 30,000 emergency room visits each year, impact 11 million Americans, including 3 million children.[45]

As one example, development of soybeans genetically engineered to produce a Brazil nut protein was abandoned after testing revealed that the protein was allergenic; people with tree nut allergies who consumed foods containing derivatives of these soybeans would likely have suffered allergic reactions.[46] While these GE soybeans never came to market, GE corn may be causing food allergies today, unbeknownst to allergy sufferers. Most U.S. corn is genetically engineered to produce insecticidal proteins derived from the soil bacterium *Bacillus thuringiensis* (*Bt*).[47] Scientists advising the Environmental Protection Agency (EPA) have found that these *Bt* proteins "could act as antigenic and allergenic sources."[48] Hundreds of allergic

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[43] Comments from Dr. Linda Kahl, FDA Compliance Officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, Regarding "Statement of Policy: Foods from Genetically Modified Plants" 2 (Jan. 8, 1992).

[44] For two of dozens of scientific reports on this issue, *see*, Food and Agric. Org. of the United Nations (FAO-WHO), *Evaluation of Allergenicity of Genetically Modified Foods: Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived from Biotechnology* (2001), *available at* ftp://ftp.fao.org/es/esn/food/allergygm.pdf; Gijs A. Kleter & Ad ACM Peijnenburg, *Screening of transgenic proteins expressed in transgenic food crops for the presence of short amino acid sequences identical to potential, IgE-binding linear epitopes of allergens*, 2 BMC STRUCTURAL BIO. 8 (2002), *available at* http://www.biomedcentral.com/1472-6807/2/8.

[45] U.S. Envtl. Prot. Agency, *EPA Grant to University of Chicago for Research on Food Allergy Triggers* (July 23, 2009), *available at* http://yosemite.epa.gov/opa/admpress.nsf/bd4379a92ceceeac8525735900400c27/ed584ff1c2e1162a852575fc00536790!OpenDocument.

[46] Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688-692 (1996).

[47] In 2015, eighty-one percent of U.S. corn (71.3 million acres) contained one or more insecticidal toxins. *See* U.S. Dept. of Agric., *Adoption of genetically engineered crops in the United States, 1996-2015*, http://www.ers.usda.gov/ media/185551/biotechcrops_d.html (last visited May 9, 2016).

[48] U.S. Envtl. Prot. Agency FIFRA Scientific Advisory Panel, SAP Report No. 2000-07, *Bt Plant-Pesticides Risk and Benefits Assessments* 76 (2000), *available at* https://archive.epa.gov/scipoly/sap/meetings/web/pdf/octoberfinal.pdf.

reactions reported in 2000 and 2001 may have been caused by exposure to GE StarLink corn.[49] In 2009, EPA funded research to develop better methods to assess the food allergy risks posed by GE crops, in particular the pesticidal corn varieties discussed above that the Agency has been approving since the mid-1990s.[50]

GE organisms have likely had other adverse impacts. FDA scientists have warned that GE organisms could have "increased levels of known naturally occurring [plant] toxicants," "new, not previously identified toxicants," and "reduced levels of nutrients," among other adverse alterations.[51] For instance, the novel use of GE bacteria to produce tryptophan, a sleeping aid, is likely responsible for an outbreak of deadly eosinophilia myalgia syndrome, which killed dozens and injured thousands in the late 1980s and early 1990s.[52] Experimental GE yeast intended for use in food processing was unexpectedly found to contain high levels of the extremely toxic and mutagenic compound methylglyoxyl.[53] Unexpected changes found in GE plants include necrotic lesions in wheat and increased levels of toxic glycoalkaloids in potatoes.[54] Rats fed for two years (lifetime study) with GE corn had a higher incidence of tumors than rats fed conventional corn.[55] Scientists also caution that the use of antibiotic resistance marker genes in some genetically engineered crops may exacerbate the serious problem of antibiotic-resistant bacteria.[56] Because GE products are mixed indiscriminately with "natural" ones, however, GE

[49]U.S. Envtl. Prot. Agency FIFRA Scientific Advisory Panel, SAP Report No. 2001-09, *Assessment of Additional Scientific Information Concerning StarLink Corn* (2001), *available at* https://archive.epa.gov/scipoly/sap/meetings/web/pdf/julyfinal.pdf; *see also* William Freese, *The StarLink Affair, Submission by Friends of the Earth to the FIFRA Scientific Advisory Panel considering Assessment of Additional Scientific Information Concerning StarLink Corn* (2001).
[50] *See* U.S. Envtl. Prot. Agency, *supra* note 45.
[51] *See, e.g.*, Memorandum from FDA Divisions of Food Chemistry & Technology and Contaminants Chemistry, to James Maryanski, FDA Biotechnology Coordinator 15 (Nov. 1, 1991), *available at* https://www.regulations.gov/#!documentDetail;D=FDA-2011-P-0723-0001.
[52] E.M. Kilbourne et al., *Tryptophan Produced by Showa Denko and Epidemic Eosinophilia-Myalgia Syndrome*, 46 J. RHEUMATOL SUPPL. 81-88 (1996); David Schubert, *A Different Perspective on GM Food*, 20 NATURE BIOTECH. 969 (2002).
[53] Tomoko Inose & Kousaku Murata, *Enhanced Accumulation of Toxic Compound in Yeast Cells Having High Glycolytic Activity: A Case Study on the Safety of Genetically Engineered Yeast*, 30 INTL. J. FOOD SCI. TECH. 141, 141-146 (1995).
[54] *See* Harry A. Kuiper et al., *Assessment of the Food Safety Issues Related to Genetically Modified Foods*, 27 PLANT J. 503-528; FAO-WHO, *supra* note 44.
[55] Gilles-Eric Séralini et al., *Republished Study: Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize*, 26 ENVTL. SCI. EUR. 14 (2014). http://enveurope.springeropen.com/articles/10.1186/s12302-014-0014-5.
[56] Jan-Peter Nap et al., *Biosafety of Kanamycin-Resistant Transgenic Plants*, 1 TRANSGENIC RES. 239, 239-249 (1992).

food labeling and a system of post-marketing surveillance[57] would be required to definitively prove human health harms from GE foods.[58]

In view of these risks, FDA scientists in the early 1990s recommended that each new GE food be tested using genotoxicity assays and animal feeding trials.[59] Others have advocated a similar testing regime,[60] while European food safety experts urge use of sophisticated profiling techniques capable of detecting novel toxins.[61] These recommendations of FDA working scientists and others have been entirely ignored by FDA administrators, who crafted the "voluntary consultation" process that prevails today. Companies that develop GE crops are not required to consult with FDA or to conduct any specific tests. If they choose to consult FDA, the Agency does not respond by approving the GE crop as safe, but rather issues a "no questions" letter that explicitly makes the company (not FDA) responsible for the safety of the GE food.[62]

Long-standing, time-tested procedures used to vet traditionally-bred, "natural" crops have been largely successful in safeguarding the food supply. The same cannot be said of GE foods, which pose greater food safety risks but are not adequately assessed by food safety authorities.

ii. The Patentability of GE Foods Shows They Are Not Natural

GE foods produced using recombinant DNA technology must differ meaningfully from their conventional counterparts because they are patentable. To be patentable, a genetically engineered food must be "new" and "novel."[63] Thus, a product or process that is patentable cannot be both "novel" for patent purposes yet "substantially equivalent" to existing technology in other contexts.

The U.S. Patent Office has granted many patents for novel genes and biotechnological tools used to develop GE plants. These novel genes and tools indisputably make the corresponding GE plants novel organisms. For instance, Monsanto's Roundup Ready soybean

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[57] Kuiper, *supra* note 54, at 520.
[58] Consumers Int'l, *Consumer rights victory as US ends opposition to GM labeling guidelines*, (July 5, 2011), http://www.consumersinternational.org/news-and-media/news/2011/07/gm-labelling-victory-as-us-ends-opposition#.Uk90phZXaa4.
[59] Memorandum from Samuel I. Shibko, Director, FDA Division of Toxciological Review and Evaluation, to James Maryanski, FDA Biotechnology Coordinator (Jan. 31, 1992); Memorandum from FDA Divisions of Food Chemistry & Technology and Contaminants Chemistry, *supra* note 51.
[60] William Freese & David Schubert, *Safety Testing and Regulation of Genetically Engineered Foods*, 21 BIOTECH. AND GENETIC ENGINEERING REVIEWS 299 (2004), *available at* http://www.centerforfoodsafety.org/files/freese_safetytestingandregulationofgeneticallyebgineeredfoods_nov212004_62269.pdf.
[61] Kuiper, *supra* note 54, at 511.
[62] William Freese, *Regulating Transgenic Crops: Is Government Up to the Task?*, FOOD AND DRUG LAW INST. Jan.-Feb. 2007, at 17, *available at* http://www.centerforfoodsafety.org/files/fdli-paper--jan-feb-2007_31582.pdf.
[63] *See* 35 U.S.C. §§ 102, 103.

(one of the world's most widely-planted GE crops) contains a patented bacterial gene[64] joined to a DNA sequence from the cauliflower mosaic virus that together form a patented "chimeric gene."[65] Introduction of this chimeric gene makes the soybean able to survive direct application of glyphosate, the active ingredient in Monsanto's Roundup herbicide. Both the presence of this chimeric gene and the ability to survive application of Roundup are characteristics that are novel to plants. Monsanto's patent application for "chimeric genes" states that "despite the efforts of numerous research teams, prior to this invention no one had succeeded in (1) creating a chimeric gene comprising a plant virus promoter coupled to a heterologous[66] structural sequence and (2) demonstrating the expression of such a gene in any type of plant cell."[67] Further, the novel chimeric gene and new glyphosate-resistance trait it confers enable a novel agricultural practice —"a method for selectively controlling weeds in a field [by] applying to the [glyphosate-resistant] crop and weeds in the field a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the crop."[68]

GE insect-resistant plants contain a variety of genes derived from the *Bt* soil bacterium. Plants containing these *Bt* genes produce one or more insecticides in all of their tissues that kill certain insect pests.[69] The presence of both the *Bt* genes and the corresponding insecticides in plant tissues are novel plant characteristics, a fact that has enabled the crop developers to secure patents on these crops.[70]

Both GE foods and the recombinant DNA techniques that produce them are novel enough to be patentable, and therefore are substantially different from traditionally produced foods. The novel trait can also enable a new and patentable agricultural practice. Accordingly, continuing to treat GE foods as novel for patenting purposes but "natural" for labeling purposes would be arbitrary and capricious.

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[64] U.S. Patent No. 5,633,435 (issued May 27, 1997); *reissued as* U.S. RE39, 247 (issued Aug. 22, 2006) (both entitled *Glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases* and assigned to Monsanto).

[65] U.S. Patent No. 5,352,605 (issued October 4, 1994) (*Chimeric Genes for Transforming Plant Cells Using Viral Promoters* and assigned to Monsanto). The key feature of this patent is the cauliflower mosaic virus promoter. All genes, including plant genes, naturally come with promoters (on-switches), which furnish a means for the organism/cell to turn the gene on when needed to produce a protein. However, genetic engineers discovered that promoter sequences from viruses were much more effective on-switches than natural plant gene promoters in the transgenic context of engineering a foreign gene into a plant.

[66] In this context, "heterologous" means that the plant virus promoter is linked to a gene derived from a different species, *i.e.*, not the cauliflower mosaic virus.

[67] U.S. Patent No. 5,633,435, *supra* note 64. In this context, "expression' means production by the plant cell of the protein encoded by the gene engineered into the plant (*e.g.* the protein conferring glyphosate resistance).

[68] *Id.*

[69] *See, e.g.*, U.S. Patent No. 6,943,282 (issued Sept. 13, 2005) (entitled *Insect Resistant Plants* and assigned to Mycogen Plant Science, Inc. (a division of Dow)).

[70] *Id.*

iii. Allowing Products Labeled as "Natural" to Contain GE Foods is Misleading to Consumers

As previously explained, the term "natural" misleads consumers; however, labeling GE foods as "natural" is particularly deceptive and misleading. A reasonable consumer would not expect foods labeled "natural" to contain novel "[p]lants or animals that have had their genetic makeup altered to exhibit traits *that are not naturally theirs*."[71] Rather, the label "natural" connotes foods from plants and animals that have only their natural complement of traits, not entirely new ones never before exhibited by the species, such as the ability to produce bacterial insecticides or survive spraying with a powerful herbicide. Indeed, sixty percent of consumers believe foods bearing the "natural" label do not contain genetically engineered ingredients.[72] Furthermore, there is no way for consumers to detect whether or not a product contains GE foods from a visual inspection alone. Consumers are misled when foods with highly unnatural characteristics such as these are labeled as natural. As a result, false advertising litigation has cropped up around the country in response to companies that label GE foods as "natural,"[73] and courts have stated that "it is not unreasonable . . . for a consumer to believe that non-organic foods labeled as 'All Natural' do not possess [ingredients from] GMOs."[74]

Moreover, the uncertainty surrounding GE foods influences consumer purchases. Studies have indicated that consumers, particularly Americans, are willing to pay substantial price premiums in order to avoid GE foods.[75] Because most consumers would not expect foods labeled

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[71] *See* Monsanto, *supra* note 41 (emphasis added).
[72] Consumer Reports, *supra* note 7, at 6.
[73] *See, e.g.*, *In re ConAgra Foods, Inc.*, 90 F. Supp. 3d 919, 939 (C.D. Cal. 2015); *In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-md-2413, 2013 WL 4647512 (E.D.N.Y. Aug. 29, 2013); Randolph v. J.M. Smucker Co., No. 13-80581, 2014 WL 1018007 (S.D. Fla. Mar. 14, 2014).
[74] *Ault v. J.M. Smucker Co.*, No. 13-CV-3409 (PAC), 2014 WL 1998235, at *6 (S.D.N.Y. May 15, 2014).
[75] *See* Wen S. Chern et al., *Consumer Acceptance and Willingness To Pay for Genetically Modified Vegetable Oil and Salmon: A Multiple-Country Assessment*, 5 AGBIOFORUM 105, 108 (2002) (reporting survey evidence of willingness to pay price premiums for non-GM vegetable oil ranging from fifty to sixty-two percent for American respondents); Catherine A. Mendenhall & Robert E. Evenson, *Estimates of Willingness To Pay a Premium for Non-GM Foods: A Survey*, (2002); MARKET DEVELOPMENT FOR GENETICALLY MODIFIED FOODS 55, 58 (Vittorio Santaniello et al., eds., 2002) (reporting that fifty percent of survey respondents stated that they were very likely or somewhat likely to purchase non-GM foods at a premium of up to twenty percent); Matthew Rousu et al., *Are United States Consumers Tolerant of Genetically Modified Foods?*, 26 REV. AGRIC. ECON. 19 (2004) (finding reduced consumer willingness to pay for food containing genetically modified material); Abebayehu Tegene et al., *The Effects of Information on Consumer Demand for Biotech Foods: Evidence from Experimental Auctions*, USDA Technical Bull. No. 1903 at 24 (Mar. 2003) (finding that American consumers discount their willingness to pay for GM-labeled foods by up to fourteen percent under a variety of information settings); *see also* Charles Noussair et al., *Do Consumers Really Refuse To Buy Genetically Modified Food?*, 114 ECON. J. 102, 112, 117-18 (2004) (reporting that thirty-five percent of French consumers are unwilling to purchase GM foods and that forty-two percent demand a

as "natural" to contain any GE content, consumers are deceived into paying premiums for "natural" foods that do not possess the qualities for which they are paying the premium. Given the wide reach of consumer concerns over GE foods, and the deceptive nature of foods labeled "natural" that have ingredients derived from GE organisms, the proper response from FDA should be to prohibit GE foods from being labeled as "natural."

Conclusion

Because the term "natural" misleads consumers to such an extent that it cannot serve a useful purpose, FDA should prohibit using the term "natural" and its variations from human food labels. In the alternative, if FDA chooses to define the term "natural," the Agency should engage in the notice-and-comment rulemaking process required by the APA to ensure public participation and transparency. In that case, given the considerable consumer confusion surrounding the term "natural," engaging the public and providing ample opportunity for public participation would be especially important and would help ensure the definition adheres to consumer expectations. In addition, any definition of "natural" FDA promulgates should restrict use of the term to single-ingredient foods. If FDA chooses to promulgate a definition of "natural," FDA should prohibit GE foods from being labelled as "natural," in keeping with generally accepted usage of the term, as well as consumer expectations.

Thank you for the opportunity to provide comments.

Respectfully Submitted,

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price reduction in order to be willing to purchase GM foods); Jill J. McCluskey et al., *Consumer Response to Genetically Modified Food Products in Japan,* 18 Wash. State Univ. Research Paper TWP-2001-101 (2001) (finding that consumers in Japan are willing to pay a premium of approximately sixty percent for non-GM noodles and tofu), *available at* http:// impact.wsu.edu/ research/twp/01-101.pdf.