Docket No. FDA-2014-N-1207

COMMENTS

of

WASHINGTON LEGAL FOUNDATION

to the

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH & HUMAN SERVICES

Concerning

USE OF THE TERM "NATURAL" IN THE LABELING OF HUMAN FOOD PRODUCTS; REQUEST FOR INFORMATION AND COMMENTS

IN RESPONSE TO THE PUBLIC NOTICE PUBLISHED
AT 80 *FED. REG.* 69905 (November 12, 2015)

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
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Re: Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments
80 Fed. Reg. 69905 (November 12, 2015)

Dear Sir/Madam:

Washington Legal Foundation (WLF) appreciates the opportunity to submit these comments in response to the Food and Drug Administration's solicitation of information on use of the term "natural" in the labeling of human food products. WLF strongly supports action by FDA to create a uniform national policy regarding use of the term "natural" on food labels.

Consumer interest in foods that are "natural" has increased in recent decades. A multi-billion-dollar "natural" food industry has emerged in response to that consumer demand. But the absence of a uniform nationwide definition of "natural" has led to consumer confusion and hampered the ability of businesses to operate efficiently. Individual States—operating both legislatively and through their tort laws—have stepped into the breach by creating their own definitions of "natural." But those actions have simply exacerbated the confusion.

The only realistic solution is for FDA to initiate a rulemaking process with the goal of creating (in conjunction with other federal agencies, including the U.S. Department of Agriculture) an overarching, uniform policy governing use of the term "natural." FDA should

then state explicitly that state labeling rules are preempted to the extent that they are not identical to FDA's policy.

WLF recognizes that "natural" is not a one-size-fits-all term. "Natural" is a term whose commonly understood meaning varies greatly depending on the qualities of the particular food at issue, as well as historical practices concerning the food.[1] As the Federal Trade Commission has explained, "the context in which 'natural' is used determines its meaning," and "it is unlikely that consumers expect the same thing from a natural apple as they do from natural ice cream." 48 Fed. Reg. 23270 (May 24, 1983). Accordingly, it may well not be possible for FDA to set out a detailed definition that provides precise guidance regarding proper use of the term in all possible factual situations. WLF urges FDA not to attempt to do so but rather to create a series of "safe harbors"—that is, a comprehensive policy setting forth a list of specific "natural" claims that could not be the basis of a "misleading" labeling claim under federal or state law.

WLF recommends that the comprehensive policy be based on the "informal" policy that FDA described in its 1991 proposed rule on food labeling: "In its informal policy, the agency has considered 'natural' to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be there." 56 Fed. Reg. 60421, 60466 (Nov. 27, 1991). That policy has guided numerous

[1] For example, based on long-established practices unique to cheese making, the cheese industry readily distinguishes between "natural" cheese and "processed" cheese. There is no reason for either FDA or the U.S. Department of Agriculture to revisit accepted definitions of "natural" cheese, given the absence of evidence of consumer confusion regarding use of that term.

manufacturer labeling decisions for the past 25 years, and many consumers—to the extent that they have focused on the term—understand "natural" to connote that no artificial or synthetic ingredients have been added to the food. But WLF is far less concerned about the precise details of the "natural" definition adopted by FDA than it is with the urgency of the need to create *some* uniform definition. Until uniformity is established, manufacturers will be reluctant to provide consumers with valuable information regarding their products for fear that doing so will generate costly litigation.

The "natural" determination ought to focus on processes applied to food after it has been produced on farms. The extent of processing is an important variable in determining whether processed food can qualify as "natural"; FDA should not permit food to be so classified if it has undergone more processing than a typical consumer would reasonably expect. On the other hand, because the term "natural" connotes something that is produced from the soil (not in a laboratory), FDA's definition should not focus on the manner in which raw agricultural products are produced. Products grown on a farm and later supplied to consumers with only minimal processing fit comfortably within commonly understood definitions of "natural," without regard to the breeding method employed. Thus, an unprocessed boysenberry still qualifies as "natural" even though it is the product of genetic modification—that is, a boysenberry is a hybrid fruit, a cross between a raspberry and a blackberry (and sometimes, a loganberry).

WLF strongly disagrees with those, such as Consumers Union, who point to non-uniform use of the term "natural" as a reason why FDA ought to ban its use on food labels. Such bans

are inconsistent with the First Amendment. The Supreme Court has repeatedly held that commercial speech bans must be a last resort, to be employed only after exhausting all other means of ensuring that consumers are not misled. Because FDA could adopt numerous other measures to prevent confusion, a ban on use of "natural" is constitutionally impermissible. At least as importantly, such a ban would cripple a vibrant industry and would ill-serve consumers, who have demonstrated a keen interest in purchasing food products that satisfy the commonly understood definitions of "natural" food.

I. *Interests of WLF*

Washington Legal Foundation is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to promoting economic liberty, free enterprise, a limited and accountable government, and the rule of law. In particular, WLF has regularly appeared in federal courts to support reasonable limitations on tort suits to recover damages from food manufacturers for allegedly inaccurate product labeling. *See, e.g.*, *Kane v. Chobani, Inc.*, __ F.3d __, 2016 WLF 1161782 (9th Cir., Mar. 24, 2016); *Young v. Johnson & Johnson*, 525 Fed. Appx. 179 (3d Cir. 2013). WLF also regularly litigates in support of the First Amendment speech rights of market participants. *See, e.g., Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

A vibrant natural-foods industry has developed in recent decades in response to increasing consumer demand for "natural" products that do not contain artificial or synthetic

ingredients. WLF is concerned, however, that industry's ability to continue to meet that demand is threatened by opportunistic plaintiffs' lawyers. They have taken advantage of the absence of a uniformly accepted definition of "natural" to deluge food manufacturers with state-law tort suits raising claims that food labeling is misleading. WLF is aware of at least several hundred such lawsuits, many of them pending in federal courts in California. WLF supports FDA adoption of a comprehensive, nationwide definition of "natural," both to reduce the possibility that some consumers will be misled and to provide manufacturers with clear guidance that will permit them to avoid potentially ruinous tort claims.

II. *The FDCA Authorizes FDA to Establish Nationwide Standards Governing Food Labeling*

As FDA has recognized, the word "natural" is often used to convey that a food is composed only of substances that are not manmade. *See* 56 Fed. Reg. at 60466. Many consumers state that they are more likely to purchase such foods. If a "natural" claim is included on a food label, the Food, Drug, and Cosmetic Act authorizes FDA to police the accuracy of the claim. 21 U.S.C. § 343(a)(1) (a food shall be deemed misbranded if "its labeling is false or misleading in any particular.").

FDA has requested comment on "whether we should establish a meaningful definition for 'natural' so that this term would have a common consumer understanding." 80 Fed. Reg. at 69906. WLF submits that the answer is "yes," FDA should establish just such a meaningful definition. WLF further submits that FDA's definition would not provide the term "natural" with the desired "common consumer understanding" unless all conflicting understandings were

explicitly preempted. In the absence of preemption of non-identical state-law definitional requirements, any possibility of creating "a common consumer understanding" of "natural" would evaporate—food manufacturers would be obliged to conform their use of the term to the potentially conflicting requirements of each State in which they conducted business.

Congress has expressly preempted a broad array of state-law food labeling requirements that are not identical to FDA labeling requirements. *See* 21 U.S.C. § 343-1 (entitled, "National uniform nutrition labeling"). Moreover, any state-law labeling requirement is impliedly preempted to the extent that it "stands as an obstacle to the accomplishment and execution of the full purposes" of federal law, *English v. General Electric Co.*, 496 U.S. 72, 79 (1990)—such as a purpose to create a nationwide "common consumer understanding" of the term "natural." Because the existence of conflicting state-law understandings of "natural" would so clearly "stand as an obstacle" to efforts to establish a uniform definition of "natural," FDA could spare all involved the cost of litigating the preemption issue by stating explicitly in its regulation that all non-identical definitions of "natural" are preempted.

III. *A Uniform Definition of "Natural" Is Necessary to Lessen Consumer Confusion and to Ensure that Conflicting State-Law Definitions Do Not Deter Manufacturers from Providing Consumers with Sought-After Information about Food Offered for Sale*

It is well understood within the food industry that there exists widespread consumer interest in purchasing "natural" foods. U.S. sales of food marketed as "natural" totaled at least $22 billion in 2014, and the growth rate for "natural" food sales has repeatedly topped 10% annually. While consumers harbor diverse views regarding the essential characteristics of

"natural" food, one overriding theme stands out: consumers expect "natural" food to contain no artificial or synthetic ingredients. As noted above, however, FDA has declined to provide any comprehensive definition of the term. In the absence of FDA direction, courts (applying state tort law) and state legislatures have begun to supply their own definitions. The inevitable result: multiple, mutually inconsistent definitions of "natural" food are announced, and the potential for consumer confusion increases.

Twenty-five years ago, when annual sales of "natural" foods were far smaller than today, FDA declined to undertake a "natural" rulemaking "[b]ecause of resource limitations and other agency priorities." 58 Fed. Reg. at 2407. The agency nonetheless recognized that a uniform definition could be of considerable value to consumers:

> The term "natural" is used, however, on a variety of products to mean a variety of things. Because of its widespread use, and the evidence that consumer regard many uses of this term as non-informative, the agency is considering establishing a definition for this term. FDA believes that if the term "natural" is adequately defined, the ambiguity surrounding use of the term that results in misleading claims could be abated.

56 Fed. Reg. at 60466. Given that use of the term "natural" on food labels has become even more widespread in the ensuing 25 years, WLF submits that the reasons for adopting a comprehensive definition are even more compelling today.

The natural food industry has built up around the concepts embodied in FDA's "informal" policy regarding the meaning of "natural" on food labels. FDA has stated, "[T]he agency has considered 'natural' to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be

expected to be there." 56 Fed. Reg. 60421, 60466 (Nov. 27, 1991). Accordingly, strong policy reasons exist for basing a comprehensive definition of "natural" on the existing informal policy. The reliance interests (among manufacturers) and the existing, general understanding of the meaning of "natural" (among consumers) created by FDA's informal policy counsel against any radical re-working of that policy. One plausible approach is the one suggested by Sarah Lee Corporation in its 2007 Citizen Petition. Sarah Lee suggested that FDA (working in conjunction with USDA) begin by adopting the following "unified policy" governing use of the term natural:

> [T]he term "natural" may be used to describe a food . . . that does not contain any artificial flavor or flavoring, coloring ingredient (regardless of source), or any artificial or synthetic ingredient that is included within or not normally expected to be in the product. The degree of processing necessary to produce the food or food ingredient should be considered in determining consumer expectation.

Citizen Petition FDA-2007-P-0007 (filed April 9, 2007). FDA could then flesh out its regulation by identifying specific ingredients whose presence: (1) would or would not be deemed to be "not normally expected to be in the product"; and (2) would or would not preclude a "natural" claim by virtue of the extent to which the ingredient has been processed.[2] While it may not be practicable to create a comprehensive regulation that addresses the application of the term "natural" to all possible product formulations, a regulation that creates safe harbors of the sort outlined above would significantly reduce potential consumer confusion.

The precise details of a comprehensive FDA regulation are less important to WLF,

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[2] WLF takes no position regarding whether any specific food ingredient is so highly processed that it should no longer be deemed a "natural" food. WLF concurs that a food is no longer "natural" when processing causes a change in the fundamental character of the food.

however, than that FDA establish *some* uniform definition of the term "natural." The absence of a uniform definition has spawned hundreds of opportunistic class-action lawsuits seeking huge damage awards for allegedly misleading "natural" claims. FDA can and should work to reduce the number of such lawsuits, by establishing a uniform policy that will allow manufacturers to make "natural" claims without fear that doing so will generate costly litigation. A consistent, easy-to-understand federal policy will also provide manufacturers with greater incentives to produce more products of the sort that many consumers are demanding: products that contain no artificial or synthetic ingredients. Moreover, a uniform policy would reduce compliance costs (and thus reduce retail prices) by subjecting food manufacturers to a single regulatory scheme for all foods.

FDA's existing informal policy has never equated a "natural" claim with a claim that the food in question provides health benefits. That policy corresponds with consumer expectations. Many consumers prefer to purchase "natural" food not because they view it as healthier but because they prefer a lifestyle and a food delivery system that eschews reliance on artificial, chemical ingredients. WLF therefore sees no reason to complicate the "natural" analysis by incorporating an evaluation of a product's health benefits. Manufacturers should be free, of course, to make *truthful* "healthy" claims as well as "natural" claims on their food labels, but we have seen no evidence to suggest that most consumers deem "natural" food to be healthier or more nutritious than food not labeled "natural."

IV. *Food Production Methods Are Not Relevant to the "Natural" Analysis*

FDA examines food-production methods to ensure that they do not compromise the food's safety. But historically it has not taken those methods into account when determining whether a food qualifies as "natural." WLF sees no reason to alter that approach now.

As FDA's Request for Information explained:

> When we established our policy concerning the use of the term "natural," it was not intended to address food production methods, such as the use of genetic engineering or other forms of genetic modification, the use of pesticides, or the use of specific animal husbandry practices.

80 Fed. Reg. at 69906. Thus, in response a question posed by FDA, WLF opposes defining "natural" in terms of whether specific production methods—for example, genetic engineering, hybridization, or use of pesticides—were employed.

The "natural" inquiry has always focused on what happens to food between the time it leaves the farm and the time it arrives on one's dinner plate. Food has traditionally been deemed "natural" if it remains largely unchanged during the journey from farm to plate. Nothing about farm production methods (*e.g.*, the farmer's use of seeds that are the product of genetic engineering) alters the "natural" inquiry. The irrelevance of production methods to that inquiry is reinforced by FDA's consistent position that the use of genetic engineering in plants is a production method that it not materially different from other methods of genetic modification used in plant breeding. *See* November 19, 2015 letter from FDA to Center for Food Safety (denying Citizen Petition No. FDA-2011-P-0723, which sought mandatory labeling of all genetically engineered foods).

Moreover, consumers interested in learning whether food was produced without using genetic engineering or pesticides have other means of discovering the information. For example, manufacturers are entitled to label their food "GMO-Free," and an increasing number do so. Moreover, manufacturers are entitled to list their products as "organic" only if they do not utilize genetic engineering and limit themselves to natural pesticides.

WLF recognizes that many commentators have urged FDA to bar the use of the term "natural" for food produced using genetic engineering. But among the numerous comments that we have read, the invariable assertion is that the commenter opposes use of genetic engineering to produce food and thus is offended by use of the term "natural" to describe food produced in that manner. Not one commenter asserts that he has been misled by use of the term "natural" on a product that he later discovered had been produced using genetic engineering. Consumers seeking to avoid products produced using genetic engineering and chemical pesticides can do so without difficulty by looking for the word "organic." Consumers will have *less* ready access to information if FDA alters the definition of "natural" such that it becomes largely synonymous with "organic."

V. *FDA Should Reject Requests to Ban Use of the Term "Natural" on Food Labels*

In June 2014, Consumers Union filed a Citizen Petition with FDA, requesting that FDA adopt a rule prohibiting the "natural" label on foods. *See* Citizen Petition No. FDA-2014-P-1650-0002. The Petition asserts, based on an April 2014 consumer survey, that "a majority of U.S. consumers are misled by the 'natural' label." Petition at 2. The petition is misguided, both

as a matter of policy and as a matter of constitutional law.

The First Amendment protects commercial speech from unwarranted government regulation. *Virginia. Pharmacy Bd. v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). The government has an interest in regulating commercial speech in order to ensure that consumers are not misled. But any such regulation must be narrowly tailored; and an absolute ban on particular speech (such as a manufacturer's use of the word "natural" with respect to its product) is never deemed "narrowly tailored" if the government could achieve its policy goals without a ban. *Thompson v. Western States Medical Center*, 535 U.S. 357, 376 (2002). FDA could not meet that demanding standard with respect to "natural" claims. If FDA were worried about consumers being misled, it could require a manufacturer to include on the label the basis for its "natural" claim; *e.g.*, that "natural" does not mean the things that Consumers Union thinks it should mean. Moreover, Consumers Union's petition has done no more than demonstrate a point that no one contests: that not everyone agrees regarding the meaning of the term "natural." But choosing one definition and rejecting others is the only way that FDA can achieve its objective, which is to come up with a nationwide, unified definition of the term; and adopting a single definition is the surest way to ultimately eliminate the confusion that Consumers Union decries.

Moreover, a ban on use of the term "natural" is bad public policy, given consumers' well-documented interest in purchasing products without artificial or synthetic ingredients. The natural food industry is thriving precisely because consumers seek to make such purchases.

Banning the word "natural" would make it more difficult for consumers to locate products with the attributes they seek. Such a ban could cripple the natural foods industry and serves no rational public policy.

VI. *Conclusion*

WLF respectfully requests that FDA create a uniform national policy regarding use of the term "natural" on food labels. It should state expressly that FDA's policy preempts non-identical state policies.

Sincerely,

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