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Citizen Petition

Requesting Disclaimer on Food Labels that Claim “Natural” (21 CFR 10.30)

To:

Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Janet Woodcock, M.D.
Commissioner
Food and Drug Administration (FDA)
Department of Human and Health Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Cc:

Food Labeling and Standards Staff (HFS-820)
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740-3835

January 22, 2022

Dear Dr. Janet Woodcock,

The undersigned submits this petition under 21 CFR 10.30 of the Federal Food, Drug and Cosmetic Act to request the Commissioner of Food and Drugs to amend the Nutrition and Labeling Education Act (NLEA).

I. Action Requested

Petitioners request: Any food product claiming “natural” on its label should, immediately adjacent to that claim, include a disclaimer stating, in equal font type, color and point size:

‘Natural’ does not imply health benefits or organic production.

II. Statements of Grounds for Petitions

Background

The Food and Drug Administration (FDA) released a proposed rule (80-FR-69905) and announced a docket (FDA-2014-N-1207) on November 12th, 2015 to request information and comments regarding the use of the term “natural” in the labeling of human food products.¹ The FDA established the docket in 2015 following four citizen petitions filed between 2006 and 2014 (FDA-2014-P-0312, FDA-2014-P-1650, FDA-2007-P-0007, FDA-2006-P-0206).¹ In addition, the FDA notes that some Federal courts have requested a response from the FDA regarding whether food products containing genetically engineered ingredients and/or high fructose corn syrup may be labeled as “natural.” In the preamble of a proposed rule in the Federal Register (56 FR 60421, November 27, 1991), the FDA acknowledges the term “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 FR 60421 at 60466).¹

Although there have been over seven thousand public comments addressing the FDA’s 2015-16 docket (FDA-2014-N-1207), the FDA has not passed a regulation, definition, or prohibition regarding the use of the term “natural” on human food products.¹ Therefore, the petitioners hereby request a disclaimer to be added to all packaged food products (excluding meat, poultry, and egg products) that wish to exclaim “natural” on their label. The disclaimer statement reads, “‘Natural’ does not imply health benefits or organic production.” We propose labeling regulations in the form of a disclaimer to circumvent misunderstanding by consumers and to account for the FDA’s 1993 acknowledgment of “natural,” which disregards (1) food production methods, (2) food manufacturing methods, and (3) potential nutritional and/or health benefits.¹

A disclaimer addressing the term “natural” is the most realistic course of action to be taken at this time, until the FDA develops a policy and/or definition describing the term “natural.” Firstly, petitioners request a disclaimer prior to defining natural because defining the term “natural” in the context of food production and consumption is a

complex feat, which would require deep understanding of consumer perceptions of “natural.” For instance, “natural” is defined in Merriam-Webster as “existing in nature and not made or caused by people: coming from nature.”² However, “natural” in the context of food products can be interpreted in several ways, including as absolute, relative, macroscopic, microscopic, or as some perceived degree of wildness.³ The degree to which it is ethical to define the “term” “natural” is unclear and would require additional research, as “natural” means different things to different consumers.³⁻⁵ Lastly, a definition of “natural” may be problematic because an online survey of U.S. food consumers in 2018 demonstrated that “less than half of respondents said they trusted the FDA to define the term in a way that they would find useful in making food choices.”⁶

Previous citizen petitions have requested banning the term “natural” from food product labels, but a disclaimer is the more reasonable course of action because prohibition of language violates commercial speech rights (U.S. Const. amend I).⁷ It is imperative that some course of action be taken, such as a disclaimer, because according to a study which surveyed 85,000 consumers, naturalness in food products is important and preference for food naturalness is high.⁵ Further, the survey by Survey Sampling International of 1,290 U.S. consumers shows that more than 50% of respondents believe a food product is “natural” if it has “no preservatives,” “no hormones and antibiotics,” or “no pesticide residues.”⁶ In addition, according to the 2018 survey findings, 26% of consumers perceive natural as analogous to “organic.”⁶ Additional studies demonstrate the misconceptions of consumers in understanding “natural” on food labeling as “healthier,” “organic,” “safer,” and/or “better for the environment.”⁶ Despite consumers associating the aforementioned characteristics with the label “natural” on their packaged food products, the FDA allows the term “natural” on food products, without any definition or regulation.¹ Therefore, the FDA allows “natural” labeling that is not forthright and does not meet consumers’ perceptions.

Factual Grounds

The essence of food labels is to provide consumers with clear and simple guidance when choosing a food and beverage best for their health or need. Yet, the current policy, or lack thereof, of the FDA regarding the term “natural” on packaged food labeling has allowed ambiguity and confusion in consumers’ understanding of “natural”. A lack of distinction between “natural” and healthy from the FDA’s end often leads to consumers misassociating “natural” with healthy, organic, and additive-free food and beverages.^{5,6,8,9}

The International Food Information Council (IFIC) conducted the 2021 Food and Health Survey of 1,014 Americans aged 18-80 years between March 23 to March 31 of 2021. Data from the Survey suggests one-third (33%) of American consumers regularly buy

food and beverages labeled “natural,” either shopping in-person or online.⁸ When asked in the survey, “what would make you believe that one product was more likely to be healthier than the other?”, most consumers perceived products without chemical sounding ingredients and with an “all-natural” label to provide a healthier image, even if both products had identical Nutrition Facts panels.⁸ It is evident that consumers have a positive perception of natural labeling and associate food and beverages labeled as “natural” or “all-natural” with “healthier” and “health benefits.”

Now, more than ever, with the impact of COVID-19, health and wellness have become some of the most important driving forces in food purchasing.⁸ According to IFIC’s 2021 Food and Health Survey, healthfulness has ranked third (58%) in consumer priorities when purchasing food.⁸ More people are buying food that they believe to have a healthful impact on them, whether warranted by science or not. From the industry’s perspective, the sales of “natural” and organic foods are growing stronger, and even outpacing total food and beverage growth in the pre-pandemic era.¹⁰ Large food companies have also formed Natural and Organic sectors under their brands to meet the growing demand from consumers.¹¹ Consequently, when consumers’ misunderstanding of the term “natural” meets a growing demand for healthy foods, FDA’s policy on “natural” labeling is not efficient or even sufficient for consumers to make accurately informed choices for their health.

Legal Grounds

In 2020 alone, 220 lawsuits were filed against the food and beverage industry, 50% of which were related to false labeling claims and 10% were specific to “All Natural” claims.¹² Many of these suits were overlooked and closed due to justification that a “reasonable consumer” would not be subject to reported deceptive advertising.¹³ The Federal Trade Commission (FTC) loosely defines deceptive advertising as relying on deception of a “reasonable consumer” through three criteria:

- 1) “There must be a representation, omission or practice that is likely to mislead the consumer;”
- 2) “The representation, omission or practice must be likely to mislead reasonable consumers under the circumstances ... [and] conveys more than one meaning to reasonable consumers, one of which is false;” and
- 3) “The representation, omission, or practice must be a ‘material’ one.”¹³

For reasons cited above, use of “natural” on food labels without a disclaimer stating independence from necessarily greater healthfulness and safety classifies as deceptive advertising.¹³ This is because the representation (as “natural”) is likely to mislead the

consumer (1) acting reasonably (2) in a “material” (3) way—materiality to mean influencing consumer behavior and choice in ways that might subsequently result in injury (misguided health behavior).¹³ Studies have shown that individuals might not only choose and have a higher willingness to pay for products with the “natural” label over ones without, but prioritize such a label even over USDA Organic claims that genuinely meet the criteria many consumers falsely attribute to “natural.”^{9,13}

The petitioners acknowledge that this petition would also need to uphold the First Amendment within commercial speech regulations. The Supreme Court has two tests when regulating commercial speech, the *Central Hudson* Test and the *Zauderer* Test.¹⁴ The *Central Hudson* Test applies when the government is restricting commercial speech. The *Zauderer* Test applies when the government is compelling or requiring specific language to be stated on food labels.¹⁴ Since this petition is not suggesting to restrict commercial speech, the *Zauderer* Test would be applied.

The *Zauderer* test is based on the foundational 1985 Supreme Court case on compelled commercial disclosures, *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*.^{14,15} The *Zauderer* Standard is the standard for commercial speech when the “government affirmatively demonstrates that an advertisement threatens to deceive consumers.”^{14,15} The thresholds for the test are as follows: (1) Is the relevant speech commercial? (2) Is the statement strictly factual? and (3) Is the accuracy of the factual disclosure well established and uncontroversial?^{14,15} The first threshold is upheld since the action requested is for food labeling which is considered commercial speech. The second threshold is upheld because the action requested is factual in stating that “natural” does not equate to healthier nor organic. The third threshold is upheld since the action requested is not a controversial disclosure as stated in the factual grounds statement.^{14,15}

Since the thresholds for *Zauderer* are upheld, the Reasonable Relationship test is performed.^{14,15} The Reasonable Relationship Tests include the following questions: (1) Are the factual disclosures reasonably related to a government interest in preventing consumer deception? and (2) Is the disclosure not unduly burdensome?^{14,15} As stated above in Legal Grounds, the current “natural” claim is deceptive to consumers. Since the factual disclosure the petitioners propose is related to the government’s interest in preventing this consumer deception, it passes this portion of the Reasonable Relationship test. Additionally, due to the unburdensome brevity of the statement proposed, it passes the second portion of the Reasonable Relationship test. Therefore, this action requested would appear to pass all aspects of the *Zauderer* Test in relation to the First Amendment, with very few hurdles or burdens.

III. Environmental Impact

The petitioners hereby state that the recommendation requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 CFR Section 25.

IV. Economic Impact

Economic impact information will be submitted upon request of the commissioner.

V. Certification

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

Respectfully submitted,



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