



May 10, 2016

VIA ELECTRONIC SUBMISSION

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

Re: Docket No. FDA-2014-N-1207 for ‘Use of the Term “natural” in the Labeling of Human Food’; 80 Fed. Reg. 69905-69909 (November 12, 2015).

Dear Sir or Madam:

These comments are submitted on behalf of the Consumer Healthcare Products Association (“CHPA”) in response to the November 12, 2015 Federal Register notice entitled, “Use of the Term ‘Natural’ in the Labeling of Human Food Products; Request for Information and Comments”.¹ CHPA is the 135-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.

CHPA appreciates the opportunity to provide information relevant to use of the term “natural” in food labeling, specifically as it applies to dietary supplements, and believes that development of a formal definition of natural by the agency will help to reduce consumer confusion and provide clarity to manufacturers and marketers making claims relying upon such a definition. CHPA currently has 25 members involved in the manufacture and/or marketing of dietary supplements and thus has an interest and expertise in the subject matter.

FDA has asked for information related to use of the term natural in food labeling, including a series of 16 specific questions addressing topics such as what types of processes and ingredients should be included when defining natural and any evidence associated with consumer understanding of “natural” claims in food labeling. CHPA members support the adoption of a definition for natural in food labeling by the FDA. While we do not suggest specific processes and ingredients to consider when developing a definition for “natural”, we do encourage the agency to adopt a principled standard while maintaining flexibility to ensure that technological advances which enhance food safety do not necessarily preclude a food (*e.g.*, a dietary supplement) from being labeled as natural. Development of a clear, concise definition of natural

¹ Federal Register Vol. 218 No. 218, p. 69905-9 November 12, 2015 (updated December 28, 2015)

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would enhance clarity among consumers and ensure a level playing field among manufacturers/distributors making use of claims involving either whole food natural products or food products containing natural ingredients.

1. Should “natural” be defined through rulemaking?

As noted above, we believe that FDA should define “natural” through the rulemaking process. However, we believe that FDA should make it clear in the rulemaking that the definition of “natural” is applicable only to food labeling, and is not appropriate for other non-food products (e.g., cosmetics, personal care, household cleaners).

2. Should “natural” be prohibited in food labeling?

We do not believe the agency should prohibit the use of natural claims in food labeling. Companies should be able to use these types of claims in a responsible fashion in order to call attention to their products and ingredients. As long as all companies are held to a similar standard we believe that consumers would not be misled.

3. What types of food should be allowed to bear the term “natural”?

All food products, including a dietary supplements, meeting the established regulatory definition of “natural”, should be able to use this claim in labeling. We believe that once a standard is adopted, all food products must be held to the same standard. While dietary supplements are also foods, consumers understand that these products require processing to be made available in shelf-stable forms. FDA currently includes the term ‘natural’ in food labeling and any future rulemaking should be consistent with the current policy.²

4. Should only raw agricultural commodities be able to bear the term “natural”?

Regarding whether only raw agricultural commodities be able to bear the term, we feel that there need to be allowances for processed material. The standard should thus be clear, but contain flexibility reflecting the many processes used to manufacture food products including dietary supplements.

5. Should only single ingredient food be able to bear the term “natural”?

We do not believe that only single ingredient foods should be able to bear the term, as this would exclude combining two or more naturally-sourced ingredients independently meeting the established definition of “natural”. FDA should adopt clear guidelines on how to label foods that are made up of a combination of natural and non-natural ingredients.

6. If multi-ingredient foods should be able to use “natural” what type of ingredients would disqualify the food from bearing the term?

We encourage the agency to adopt a principled standard using the best available science to define ingredients which could be claimed to be natural. For instance, to date FDA has not

² 21 CFR 101.22; 21 CFR 101.9

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indicated any distinction between synthetically-derived vitamins/minerals and naturally-derived ones, nor do they feel that food from genetically engineered plants is inferior to food from traditionally bred plants.

Multi-ingredient products labeled as “100% natural” should be made from individual ingredients which all meet the established regulatory definition of natural. Products containing one or more ingredients that do not meet the established definition of natural should not be labeled as “100% natural”. However, a tiered approach to labeling different categories of natural products would allow for identification of the overall product or individual components as “natural”.

7. Is there any data/information suggesting that consumers associate, confuse, or compare “natural” with “organic”?

We are aware of several studies^{3,4,5} which evaluated consumer understanding of the terms “natural” and “organic”. Results from these studies demonstrate the varied consumer understanding of these terms and the need for a clearly defined standard adopted using scientifically sound principles.

8. Should certain production practices used in agriculture (genetic engineering, mutagenesis, hybridization, pesticide use, etc.) be a factor in defining “natural?”

As previously noted, the agency should focus on the development of a principled standard. We encourage the FDA to adopt a list of examples of allowed/disallowed processes, while taking into account steps routinely performed to enhance food safety.

9. Is there any data/information suggesting that consumers associate, confuse, or compare “natural” with “healthy”

While we believe that there is a varied consumer understanding of “natural”, we are not aware of any direct evidence demonstrating that consumers confuse the terms “natural” and “healthy”.

10. Should manufacturing processes (e.g., fermenting, pasteurizing, irradiating, etc.) be considered in determining when a food can bear the term “natural?”

We believe the FDA should consider manufacturing processes (e.g., fermenting, pasteurizing, irradiating, etc.) when determining when a food can bear the term “natural” and ask that the agency provide examples of what types of processes are allowed in guidance to follow formal rulemaking.

11. Should “natural” only apply to unprocessed foods?

We do not believe that a claim of “natural” should only apply to unprocessed foods. FDA should adopt a flexible, science-based approach to determine whether a particular process would

³ Consumer Reports National Research Center Survey Research Report, Natural Food Labels Survey, 2015

⁴ Hartman Group, Beyond Natural & Organic 2010

⁵ Shelton Group, Eco Pulse Survey April-May 2009

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preclude a food product (or individual ingredient) from being labeled as “natural” and should provide examples of manufacturing processes that do not alter the food (or ingredient) such that it would no longer qualify to be labeled as “natural”. Stakeholders should be afforded adequate opportunities for input on the development of any such list of manufacturing processes contributing to the definition of “natural”.

12. Should the manner in which an ingredient is produced or sourced affect whether a food containing that ingredient may be labeled as “natural?”

Regarding the manner in which an ingredient is produced or sourced and if this should affect whether a food containing that ingredient may be labeled as “natural”, we encourage FDA to focus on the origin of ingredients as well as on defining acceptable food processing steps that do not significantly alter the physical properties of an ingredient. Flexibility should be incorporated into any definition for those processes which enhance food safety.

13. What can be done to ensure that consumers have a consistent and accurate understanding of the term “natural” in food labeling to ensure that it is not misleading?

To ensure that consumers have a consistent and accurate understanding of “natural” in food labeling we believe that the FDA should undertake consumer focused education efforts once the definition is determined. Examples of such efforts could include the development of Question & Answer type documents or Consumer Health Information for inclusion on the FDA website. CHPA has extensive experience developing these types of documents and would be willing to assist the agency with these types of efforts.

14. What are the public health benefits, if any, of defining the term natural in food labeling?

While CHPA feels that it is important for the FDA to support the adoption of a healthy lifestyle which could include eating foods labeled as natural (or containing natural ingredients), we do not believe that there should be any defined health benefits associated with the term “natural” in food labeling. We are unaware of any scientific evidence supporting public health benefits associated with defining the term natural in food labeling.

15. Should “natural” have some nutritional benefit associated with it? If so, what should be the benefit? What nutrients should be considered?

We do not believe that a labeling claim of “natural” should require proof of a nutritional benefit, nor are we aware of any particular nutritional benefits associated with the term natural.

16. How might we determine whether foods labeled “natural” comply with any criteria for bearing the claim?

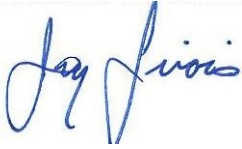
We believe that the agency may be able to determine whether products are in compliance with any criteria required for the use of a “natural” claim either through routine surveillance of marketed products or during facility inspections. We tentatively recommend that FDA enforce

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this by requesting claim support during inspections. However, due to the potential complexity of any proposed regulation, at this time we are withholding a final recommendation for agency monitoring for compliance with “natural” claims in food labeling until publication of a proposed rule.

We appreciate the opportunity to submit these comments. Please feel free to contact us should you have any questions or require additional information.

Sincerely,



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