Use of the Term “Natural” in Food Labeling

FDA’s Perspective

Patricia A. Hansen, PhD
Deputy Director
Office of Nutrition and Food Labeling
Center for Food Safety and Applied Nutrition
U. S. Food and Drug Administration
September 25, 2019
Use of the Term “Natural” in Food Labeling

• FDA’s long-standing policy

• FDA’s previous efforts to re-examine the use of the term “natural” in food labeling

• FDA’s current effort
FDA’s Long-Standing Policy on the Use of the Term “Natural”

Prior to 1990

• FDA did not try to restrict use of the term, except for added color, synthetic substances and flavors

• Under this informal policy, FDA 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
Historical Milestones in the Statutory History of Food Labeling

• 1906 – Pure Food and Drug Act
• 1938 – Food, Drug and Cosmetic Act
• 1950 – Oleomargarine Act
• 1958 – Food Additives Amendment
• 1966 – Fair Packaging and Labeling Act (FPLA)
• 1990 – Nutrition Labeling and Education Act
NLEA

- The NLEA was the driver for many new proposed labeling regulations and requests for comment on other labeling issues
  - The Nutrition Facts label
  - Nutrient content claims
  - Health claims
  - Other claims and aspects of food labeling
1991 - Citing increased industry and consumer and industry interest and data suggesting “natural” claims were misleading and confusing, FDA sought comment on how, or if, it should develop a formal definition for the term

– Do consumers and industry believe “natural” should be defined? If so, how? Examples of “natural foods”?

– Should more than “minimal processing” exclude use of the term? Examples of “minimal” processes?

– Should the use of any artificial or synthetic ingredients exclude use of the term?
Revisiting FDA’s Policy on “Natural” – the 1990’s

• 1993 – FDA stated that it would not be formally defining “natural” at that time and would maintain its long-standing policy
  – Comments received in 1991 did not provide FDA with a clear direction to follow
  – A wide range of views expressed and many different factors to consider presented
  – Limited resources and competing priorities
FDA’s Policy on “Natural” – Fast Forwarding Through the 1990’s to early 2010’s

• Questions on application of FDA policy to multiple-ingredient foods containing colors or flavors
• New ingredients
• Questions on application of FDA policy to ingredients sourced in different ways
• Production and processing methods not explicitly addressed by FDA’s long-standing policy
• Requests from stakeholders that FDA define the term “natural”
• Requests from stakeholders that FDA prohibit the use of the term “natural”
Revisiting FDA’s Policy on “Natural” – 2015

• November 2015 – Citing a number of factors, FDA issued a Request for Information and Comments (RFI) on the use of the term “natural” in food labeling
  – Changing technology and marketplace, consumer and industry interest
  – Citizen petitions requesting FDA define or prohibit use of the term “natural”
  – Court requests for administrative determinations in specific situations involving private party litigation
  – Opportunities to coordinate with USDA
FDA’s RFI on “Natural”

• The RFI posed 16 multi-part questions, covering a wide range of topics...
  – Should FDA define “natural”? Prohibit use of the term?
  – If defined, what foods should be permitted to bear the term? Only raw agricultural commodities? Only single-ingredient foods?
  – If multiple-ingredient foods are permitted to bear the term, what types of ingredients would disqualify foods from bearing the term? Should the way in which an ingredient is produced or sourced be a factor?
FDA’s RFI on “Natural”

• More on the RFI questions and topics...
  – What are consumers’ understanding and perceptions of the terms “natural” vs. “organic” or “healthy”? Are they associated?
  – Should production practices, used in agriculture, for example, be a factor in defining “natural”?
  – Should the term “natural” only apply to “unprocessed” foods? Should specific manufacturing processes be a factor in defining “natural”? If the term could include some processing methods, what should those be?
FDA’s RFI on “Natural”

• More on the RFI questions and topics...
  – What can be done to ensure that consumers have a consistent and accurate understanding of the term “natural” when used in food labeling?
  – What are the public health benefits, if any, of defining the term “natural”?
  – Should the term “natural” have some nutritional benefit associated with it? If so, what should be the benefit?
Response to FDA’s RFI on “Natural”

The RFI was of great interest and stimulated a robust response

- Comment period extended to May 2016 after many requests to extend
- More than 7,500 comments received from consumers, industry, and other stakeholders
- Some provided only a view supporting defining or prohibiting the term
- Others provided more detailed responses, addressing additional questions posed in the RFI
- Over 125 of the comments provided data and factual information in addition to detailed explanations of and rationale for their responses
Number of Responses
Number of Detailed Responses
Response to FDA’s RFI on “Natural”

High-level themes from the comments submitted

– An almost equal number of comments in support of defining “natural” as the number opposed to defining the term or did not respond to the question
– Numerous comments requested that genetically engineered (GE) foods and ingredients not be permitted to be labeled as “natural”
– Majority of comments expressed views about the use of the term “natural” that were consistent with FDA’s long-standing policy
– Wide range of views expressed on topics not currently addressed by FDA’s long-standing policy (e.g., production and processing, alignment with “organic” or “healthy”)

A wealth of information was obtained but additional information and analysis was needed
Additional work related to “natural” in 2016-2018....

• FDA consumer research

• Collaborative consumer research with IFSH

• Ongoing review of the published literature

• FDA is considering all of this information, including all information submitted to the docket on “natural” as we consider our “next steps” in this priority area
Meanwhile, on other fronts in 2015-2017....

- FDA was completing work on key priorities
  - Nutrition Facts Label
  - Menu and vending labeling

- FDA was developing a plan for the next important phase in nutrition and food labeling
Nutrition Innovation Strategy (NIS)

• March 2018 – FDA announces the NIS

• Key goals of NIS:
  – Empower consumers with information
  – Facilitate industry innovation toward healthier foods that consumers want.

• Agency is committed to engaging with stakeholders to explore how to best promote public health in the evolving food and beverage marketplace.
NIS Key Elements

• Modernizing Claims
• Modernizing Ingredient Labels
• Implementing the Nutrition Facts Label and Menu Labeling
• Reducing Sodium
• Modernizing Standards of Identity
Modernizing Claims

• Themes for this element of the NIS
  – Science-based
  – Increasing transparency and clarity

• Specific topics under this element include
  – The claim “healthy”
  – Nutrient content claims
  – Health claims
  – Other claims such as “natural”
NIS Accomplishments

• Current progress:
  – Public Meeting in 2018
  – Published final guidance documents for Nutrition Facts label and Menu labeling
  – Consumer education for menu labeling and the Nutrition Facts label
  – Published draft guidance on labeling of KCl
  – Continuing work on sodium reduction targets
We are very close to proposing a new definition for the “healthy” claim and working diligently to complete our work on the “natural” claim as well...

Stay Tuned!