2016 ASTA REGULATORY WORKSHOP

Vini Narain, ASTA President &
Carol Kitchen, ASTA Government Relations & Advocacy Committee Chair

FDA'S PATH TO DEFINING "NATURAL" AND ASTA'S ROLE

Joanna Drake, Verto Legal Solutions

Proliferation of "Natural" Products

The "Natural" History

Proposed rule for natural foods in 1974

Established an informal policy regarding the use of natural in meat and poultry products

Adopted an informal policy regarding natural


ALL
NATURAL

FDA's Request for Comments – Should the Agency Finally Define "Natural"?

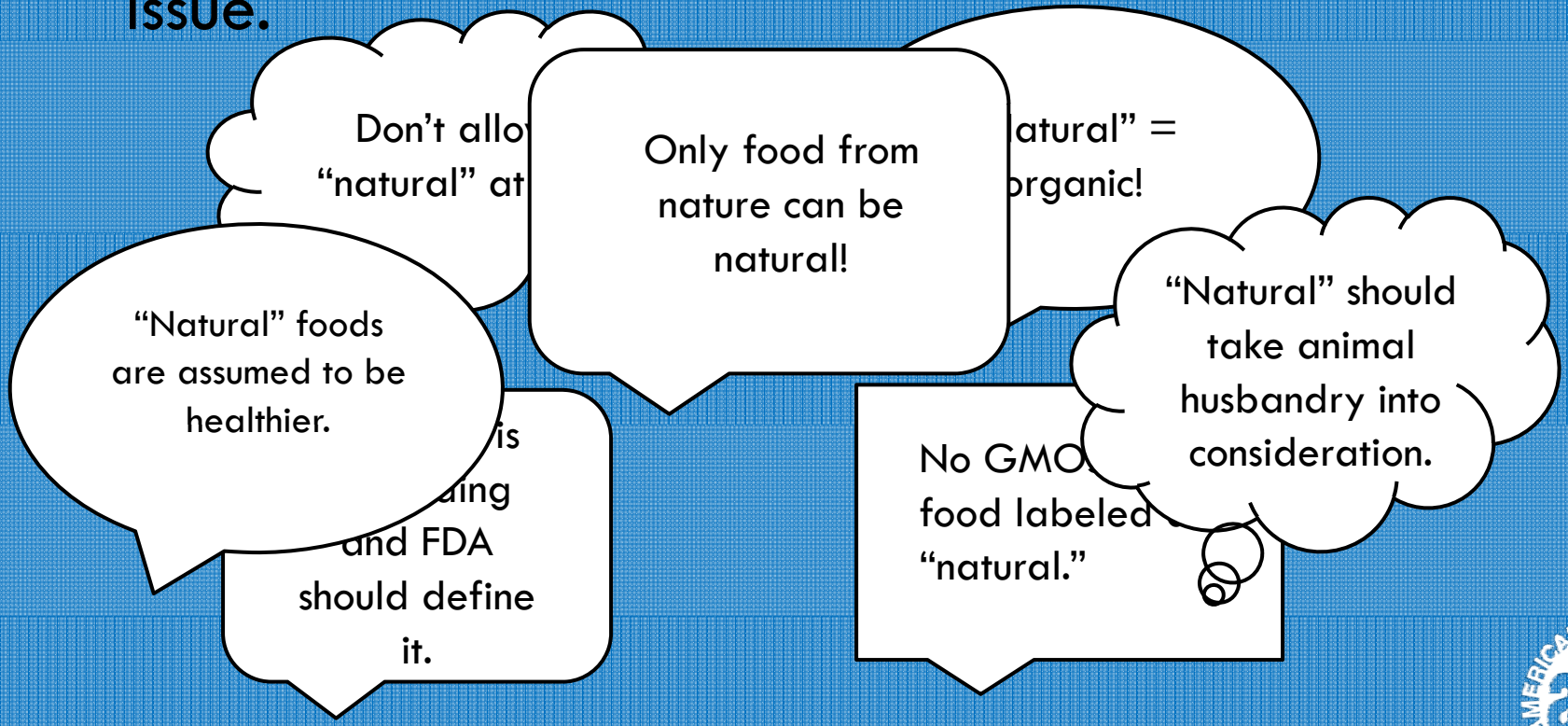
- FDA has a longstanding policy on the use of the term "natural" on labels of human food
  - FDA considers "natural" to mean that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be expected to be in the food.
- On November 12, 2015, FDA published a request for comment
  - Should FDA define "natural"?
  - Should "natural" labeling be limited in some way?
  - Should production techniques be a factor?
  - Should manufacturing processes be a factor?
  - What can be done to ensure "natural" labeling is not misleading?

Regulatory Roadmap – The Steps to Defining "Natural"

- November 12, 2015 request for information is very preliminary in the regulatory lifecycle of rulemaking.
- IF FDA decides to formally define "natural" for use on human food labels, the agency MUST embark on notice-and-comment rulemaking.
  - Very time consuming
  - Provides additional opportunities to provide comment to the agency
  - May give a baseline into agency's thoughts

"Natural" Engagement – Who Cares About It Anyway?

- Over 7,600 comments to FDA's request for comments! Significant stakeholder interest in this issue.



ASTA's Comments – An Overview

- **REMEMBER** – FDA's Request for Information and Comments is a very preliminary regulation activity and is not automatically indicative of actual rulemaking.
- ASTA submitted a robust set of comments that addressed questions relevant to the spice industry:
  - If FDA defines "natural," such a definition should be consistent with current policy and spices should be permitted in food products labeled as "natural."
  - FDA should, through notice-and-comment rulemaking, define "natural" for use in labeling human food products and permit spice to be added to food products labeled as "natural."
  - FDA should consider both single ingredient foods and multi-ingredient packaged foods eligible for "natural" labeling.

ASTA's Comments - Why They are Important?

- ASTA submitted comments to FDA's request for information – so, what does this establish?
  - Demonstrates ASTA is engaged on this issue.
  - Puts ASTA's positions in the public record - FDA is required to consider all comments – especially during the rulemaking procedure.
  - Signals to FDA that members of the regulated industry are paying attention to agency action.
  - There is an important role for ingredient trade associations like ASTA – food industry associations are only addressing packaged food issues.

Looking Ahead – Action by FDA

- FDA has signaled that it will take the agency a long time to wade through the comments to its Request for Information and Comments on the use of the term "natural" in labeling human food.

- Should we expect rulemaking?
- Should we expect a major deviation from FDA's current policy on the use of the term "natural?"
- What actions should ASTA take?

Thank you!

Questions?

Joanna R. Drake

Verto Legal Solutions

jdrake@vertolegalsolutions.net

202-331-2325