SupplySide WEST | KSM-66 Ashwagandha | SEPT 25-29 2017 LAS VEGAS

Developing and Delivering Clean Label Messaging

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AGENDA

FDA Labeling Requirements

- Just the Basics

"Clean" Labeling Trends and Considerations

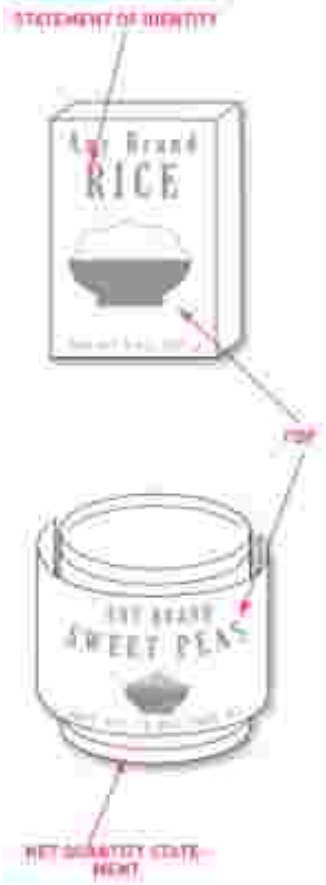
- Non-GMO
- Gluten-Free
- No Artificial Preservatives
- No Artificial Sweeteners
- Natural
- Healthy

FSMA and the Supply Chain

Questions?

Just the Basics: What is Required?

- **Statement of Identity**
  - The Name of the Food (e.g., “Rice,” “Chicken Noodle Soup”)
- **Net Quantity Statement**
  - Amount of Product (e.g., “Net Wt. 8 oz”)
- **Name and Address**
  - Manufacturer, Packer, or Distributor
- **Major Food Allergens**
  - Required to disclose presence of Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Peanuts, Wheat, and Soybeans
  - (e.g., “Contains Egg and Soy”)



FDA, Food Labeling Guide

Just the Basics: What is Required?

- **Ingredient List**
  - List each ingredient in descending order of predominance by weight (e.g., “Pinto Beans, Water, Salt”)
  - Use common or usual name
    - “Sugar” instead of “Sucrose”
- **Nutrition Facts Panel**
  - Nutrient Declarations
  - New Nutrition Facts Final Rule
    - New Format
    - New Declarations

Old

New

New Nutrition and Supplement Facts Rule: Highlights

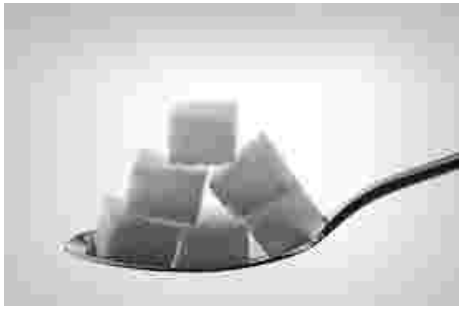
In General:

- Design Changes
- Ingredient declarations (required declarations, ingredient names, units of measure, nutrient definitions)
- Changes to DRVs/ RDIs

Hot Topics:

- "Added Sugar" must be declared and must be supported by records.
- New definition of "Dietary Fiber" –
  - If a dietary fiber is an isolated or synthetic non-digestible carbohydrate, it may only be included in the dietary fiber declaration if FDA includes the fiber on a list the agency has created.

Compliance dates have been delayed . . .



Nutrition and Supplement Facts Label Rule: Delayed Compliance Date and Alignment with GM0 Rule

- Industry groups sent a letter in March 2017 to HHS Sec. Price requesting that the Nutrition Facts final rule be delayed until May 2021.
- Among the reasons for the requested delay is the promulgation of the USDA's GMO disclosure final rule.
  - Rule must be promulgated by **2018**, but compliance date for GMO disclosure requirements are unknown.
- Industry argued that requiring compliance with Nutrition and Supplement Facts final rule by **2018** would result in multiple, costly label changes since the labels will then need to be revised to comply with the GMO final rule.
- Industry Recommended one compliance date for both rules.
- Just last week, FDA commissioner Gottlieb indicated at a conference that the new date might be around January 2020.
- Awaiting publication in the Federal Register.

STAY TUNED

“Clean” Labeling – Money Maker

Marketing Daily, Media Post, 08/24/17:

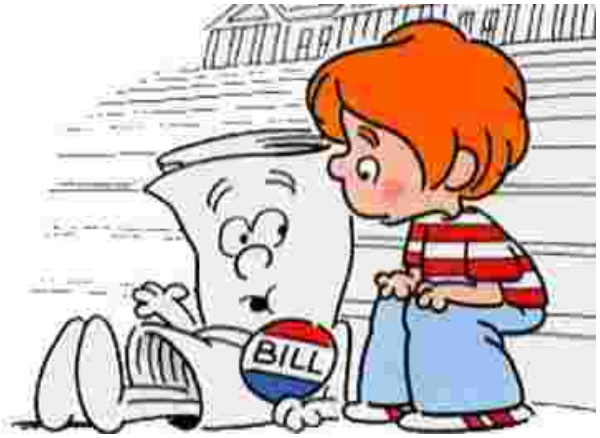
According to recent Nielsen data,

> “sales of products that make organic claims are up 10% compared to a year ago, sales of those making ‘all natural’ claims are up 7.8%, and sales of those claiming ‘no additives or artificial ingredients’ are up 8%, according to a new Nielsen report on clean labeling trends, including consumer behavior and sales results.”

> “In the food and beverages sector, across categories, products that had labels showing the claim “nothing artificial” saw sales rise 3.6% in the 52 weeks ended May 20, products claiming “all natural” were up 7.8%, and those claiming “free of additives and artificial ingredients” were up 8%.”

Clean Labeling: "GMO-FREE" "NON-GE" CLAIMS

- Patchwork state laws on GMO labeling were cropping up across the country
  - E.g., Vermont Law compelled GMO disclosures on "covered products"
- **July 2016:** National Bioengineered Food Disclosure Standard (Pub Law 114-214)
  - Preempts state laws;
  - Requires uniform disclosure of GMOs;
  - Disclosure applies to "bioengineered foods";
  - Gives USDA primary authority over labeling;
  - Requires USDA to promulgate rules by **July 2018**.
- USDA sought stakeholder input on 30 questions this summer.
- Comment period closed on August 25, but there will be more opportunities for stakeholder input during the formal rulemaking process.



Clean Labeling: "GMO-FREE" "NON-GE" CLAIMS

REGULATORY STANDARD

- "GMO-free," GE Free," "Non-GMO" and similar claims conveys zero or total absence unless a regulatory definition has been put in place in a specific situation
- Substantiation difficulty meeting "free" or "zero" claims
- FDA does not like the term "GMO"

PLAINTIFFS' BAR

- Chipotle class action alleged that it misled consumers with "Non-GMO" claims since the meat products are derived from animals fed GMO corn and soy

Clean Labeling: "GLUTEN-FREE" CLAIMS

- FDA: Inherently gluten free or does not contain an ingredient that is:
  - a gluten-containing grain;
  - derived from a gluten-containing grain that has not been processed to remove gluten; or
  - derived from a gluten-containing grain that has been processed to remove gluten, if the use of that ingredient results in the presence of 20 ppm or more gluten in the food
- General Mills Class Actions
  - Labeled Cheerios and Honey Nut Cheerios "Gluten Free"
  - FDA testing showed gluten content exceeded 20 ppm

Clean Labeling: "NO PRESERVATIVES" CLAIMS

REGULATORY STANDARD

- The term chemical preservative means any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.
- 21 C.F.R. Sec. 101.22

PLAINTIFFS' BAR

- Lean Cuisine Class Action – citric acid ingredient in product makes "No Preservative" Claim misleading.
- Does not matter whether or not citric acid is functioning as a preservative or is being used for another purpose.

Clean Labeling: "NO ARTIFICIAL SWEETENERS" CLAIMS

REGULATORY STANDARD

- Six high-intensity sweeteners approved by FDA as food additives:
  - saccharin, aspartame, acesulfame potassium (Ace-K), sucralose, neotame, and advantame
- GRAS notices submitted for two types of high-intensity sweeteners:
  - steviol glycosides obtained from the leaves of the stevia plant (Stevia rebaudiana (Bertoni) and extracts obtained from Siraitia grosvenorii Swingle fruit (Luo Han Guo or monk fruit)

PLAINTIFFS' BAR

- Lawsuits filed against ingredients derived from natural sources that plaintiffs claim have been processed and no longer natural
- Example: Class action complaint against Kraft alleging that "no artificial sweetener" claim was misleading on lemonade product because of maltodextrin ingredient

Clean Labeling: "NATURAL" CLAIMS

- The FDA has considered the term "natural" to mean that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in that food.

- However, this policy was not intended to address food production methods, such as the use of pesticides, nor did it explicitly address food processing or manufacturing methods, such as thermal technologies, pasteurization, or irradiation. The FDA also did not consider whether the term "natural" should describe any nutritional or other health benefit.

- Agency requested comments on meaning of "natural" in 2016, but has not moved forward beyond that.

Clean Labeling: "NATURAL" CLAIMS (CONT'D)

- Absent FDA clarification on "Natural," the term as been the subject of numerous lawsuits:
- Quaker Oats "100% Natural" Oatmeal
  - Traces of glyphosate (pesticide) found in the product
- Sargento "Natural" Cheese
  - Manufactured using milk from cows fed GMO feed and treated with rbST

- Nature Valley "100% Natural" Products
  - Contains ingredients (high maltose corn syrup) derived from natural sources but so highly processed that they are no longer natural

Clean Labeling: "HEALTHY" CLAIMS

- "Healthy" as a nutrient content claim suggests that a food, because of its nutrient content, may help consumers maintain healthy dietary practices.
- Claim is made in connection with an explicit or implicit claim about a nutrient.
- FDA regulations set forth specific requirements for using the term "healthy" as a nutrient content claim:
  - The food meets conditions for fat, saturated fat, cholesterol, sodium, and other nutrients; and
  - The food complies with the definition and declaration requirements 21 C.F.R. Part 101 for any specific nutrient content claim on the label or in labeling; and
  - Nutrients added to the food to meet the 10% RDI requirement are added in accordance with FDA's fortification policy.

    21 CFR 101.65

Clean Labeling: "HEALTHY" CLAIMS

- FDA currently undertaking process to redefine "healthy."
  - KIND Warning Letter and Petition
  - KIND argued that the "healthy and tasty" claim on the back of the package was not a nutrient content claim, but instead describes the company's general philosophy
- Enforcement discretion permitted when "healthy" claims made for a products:
  - Are not low in total fat, but have a fat profile makeup of predominantly mono and polyunsaturated fats; or
  - Contain at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or vitamin D
- FDA held a public meeting on March 9, 2017 to discuss defining the term "healthy."

Food Safety Modernization Act "FSMA"

- Signed into law on **January 4, 2011.**
- Regarded as the most comprehensive overhaul to the food safety system in over 70 years.
- Goal: A preventive approach to food safety, emphasizing accountability and monitoring throughout the entire production process.
- Established mandatory deadlines to finalize certain implementing rules.

Supply Chain Controls and Opportunities under FSMA

Hazard Analysis and Risk-Based Preventive Requirements (21 CFR 117):

- Covered facilities that manufacture, process, package, or hold food must develop a written food safety plan for each type of food that includes:
  - a hazard analysis;
  - preventive controls;
  - monitoring procedures;
  - a corrective action plan;
  - verification and validation activities; and
  - a supply-chain program.★

Foreign Supplier Verification Program Requirements (21 CFR 1.500):

- "Importers" must implement a Foreign Supplier Verification Program for each food imported, that includes:
  - a hazard analysis,
  - a risk evaluation of the supplier's,
  - supplier verification,★
  - monitoring, and
  - corrective action plans.

FSMA Opportunities: Supporting Source/Process Claims

- "Clean" claims often speak to processing/sourcing attributes—
  - E.g., "antibiotic free"; "no GMOs"; "no hormones"; etc.
- To support these claims, consider opportunities in supply chain provisions of FSMA requirements:
  - Strict control over the supply chain,
  - Visibility to the point of origin,
  - Validation, verification, inspection and monitoring,
  - Defined roles and responsibilities throughout the supply chain, and thorough documentation/record keeping

QUESTIONS?

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