

Brief Intro to Labeling Framework

- Labels must be truthful and not misleading. 21 U.S.C. § 343.
 - Something can be true and still be misleading.
 - "The California Supreme Court has recognized that these laws prohibit not only advertising which is false, but also advertising which, although true, is either actually misleading or which has a capacity, likelihood or tendency to deceive or confuse the public." Williams v. Gerber Prods. Co., 552 F.3d 934, 938 (9th Cir. 2008).
- Labels must comply with 21 C.F.R. pt. 101 (among other regulations in title 21)



Regulatory Update: Nutrition Facts Panel

- Final rule published May 2016
- Extended compliance date:
 - Jan. 1, 2020: \$10m or more in annual food sales
 - Jan. 1, 2021: < \$10m in annual food sales
- Some changes include:
 - Larger calorie declaration
 - No more declaration of "calories from fat"
 - Total sugar and added sugar declarations; definition of "added sugars"
 - Definition of "dietary fiber"
 - Revised micronutrient declarations



Source: FDA, Side-by-Side Comparison

Regulatory Updates on "Natural"

- No regulatory updates on "natural."
- The FDA is still operating under its long-standing policy definition.
- Comment period on defining "natural" closed in early May 2016.



Litigation Updates on "Natural"

- "Non-natural" ingredients: e.g., xanthan gum
 - Rosillo v. Annie's Homegrown, Inc.
- Ingredients derived from genetically modified crops
 - In re KIND LLC "Healthy and All Natural"
- Animals from which milk was sourced may have eaten genetically engineered food, may have been raised with hormones and certain milk production methods
 - Podpeskar v. Dannon Company, Inc.
- Non-natural flavorings and compounds
 - Rice v. National Beverage Corp. d/b/a LaCroix Sparkling Waters
- Pesticide residue
 - In re General Mills Glyphosate

Regulatory Updates on "Healthy"

- No regulatory updates on "healthy."
- The FDA's regulation on use of the implied nutrient content claim "healthy" still exists
- Comment period on defining "healthy" closed in late January 2017, and the FDA held a public meeting in March 2017.
- September 2016 guidance on regulatory enforcement on use of "healthy" in certain situations.
- Have not seen much recent enforcement of "healthy" by FDA



Litigation Updates on "Healthy"

- "Diet" claim & impact on weight loss
 - Manuel v. Pepsi-Cola Company
- Claims that products are healthy in light of sugar levels
 - Krommenhock v. Post Foods, LLC
- Coconut oil
 - Tracton v. Viva Labs, Inc.
- Presence of chemicals
 - Zeiger v. Wellpet LLC
- Pesticide residue
 - Frankel v. Bob's Red Mill Natural Foods, Inc.

Other Labeling Litigation Trends

- "Cold-Pressed," "Fresh"
 - Campbell v. Freshbev LLC
 - Campbell v. Drink Daily Greens, LLC
- "No Sugar Added"
 - Casey v. Odwalla, Inc.
 - Bruton v. Gerber Products Company
- Food/health connection

Statements of Identity

- Legal standard: The statement of identity for a food is either:
 - (1) a standard of identity established in federal law;
 - (2) the common or usual name;
 - (3) an appropriately descriptive term; or
 - (4) the fanciful name, if the nature of the product is obvious.
- <u>Current issue</u>: Plant-based foods use of terms that have or may have standards of identity (e.g., soy milk, almond milk, nut cheese and yogurt, vegan butter)

Standards of Identity - Plant-Based Foods

- CURRENT STATUS: The FDA issued a request for comment on the use of dairy terms in the labeling of plant-based products on September 28, 2018. Comments are due November 27, 2018.
- High-level topics for comment:
 - (A) The current market conditions and labeling costs of plant-based products;
 - (B) consumer understanding, perception, purchase, and consumption of plantbased products, particularly those manufactured to resemble dairy foods such as, for example, milk, cultured milk, yogurt, and cheese;
 - (C) consumer understanding regarding the basic nature, characteristics, and properties of these plant-based products;
 - (D) consumer understanding of the nutritional content of plant-based products and dairy foods and the effect, if any, on consumer purchases and use; and
 - (E) the role of plant-based products and dairy foods in meeting the recommendations in the Dietary Guidelines.

Standards of Identity – Plant-Based Foods: Timeline

- Early 2017: DAIRY PRIDE Act (Defending Against Imitations and Replacements of Yogurt, Milk, and Cheese to Promote Regular Intake of Dairy Everyday Act) – in committee in both chambers
- March 2017: the Good Food Institute submits a petition to the FDA requesting clarification about naming new foods
- August 2017: the National Milk Producers Federation submits a response to the GFI petition
- January 2018: the FDA mentions standards of identity (and potential modernization of the same) in its Strategic Roadmap
- July 2018: FDA Commissioner Gottlieb mentions the FDA's intention to examine plant-based foods' use of standarized dairy terms
- September 2018: FDA issues request for comment on use of standardized dairy terms by plant-based companies



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