2022 in Review and Preparing for 2023 at the FDA

December 14, 2022

Todd A. Harrison
Partner and Co-Chair | +1 202.344.4724 | TAHarrison@Venable.com

Claudia A. Lewis
Partner and Co-Chair | +1 202.344.4359 | CALewis@Venable.com

VENABLE LLP

Discussion Topics

- FDA Healthy Definition
- Sesame Allergen Designation
- Homeopathic Drug Product Guidance
- Updated FDA Guidance for Medical Device Software
- Bills to Watch
- Class Action Litigation Hot Topics
- Prop 65

Disclaimer: *This presentation is intended as a summary of the issues presented and is not intended to provide legal advice. It is provided for the general information of the attendees. Legal counsel and advice should be sought for any specific questions and before taking any action in reliance on the information presented.*

VENABLE LLP

FDA Proposed Rule: "Healthy" Definition

- A Healthy claim is a nutrient content claim.
- Until this point, to make a "healthy" claim, advertisers have needed to show that the product meets certain minimum nutrition standards, such as a range of acceptable total or saturated fat, cholesterol, or sodium, or certain vitamins and minerals.
  - Focus was on levels of nutrients.
- FDA's proposal would change the focus to the amount of a food group in a product.
  - A food must now contain a certain amount of food (a 'food group equivalent' (FGE)) from at least one of these recommended food groups or subgroups (fruit, vegetables, grains, dairy, and protein foods, oils, mixed products, main dish, and meals)
- The new deadline for comments is February 16, 2023.

VENABLE LLP

Significant Changes to Marketing "Healthy" Products

- Only products containing food or FGEs could qualify for a "healthy" claim
  - Dietary supplements may not qualify
- FDA's proposal would broaden the circumstances under which a claim could be considered an implied "healthy" claim.
  - "any information on the label or labeling that puts the term "healthy" into a nutritional context would make "healthy" an implied nutrient content claim when it is used to characterize the food."
  - This includes brand names

VENABLE LLP

Sesame Added as Major Food Allergen

1. Effective January 1, 2023, added as 9th major food allergen.
2. FDA published an updated guidance in November that specifically addresses allergen labeling for dietary supplements and provides Q&A on the subject.
3. When used as part of a spice blend, for example, FDA indicates that sesame may be declared using the collective term “spice” or “spices” (where its common or usual name does not appear in the ingredient list), but it should then be declared in a “Contains” statement or in a parenthetical after the collective term “spice” or “spices” in the ingredient list, i.e., “Contains sesame” or “spices (sesame).”

VENABLE LLP

FDA Guidance on Drug Products Labeled as Homeopathic

- FDA developed a risk-based approach to prioritize specific categories of homeopathic drug products that "potentially pose a higher risk to public health, such as those intended for populations at greater risk for adverse reactions, including those with weakened immune systems, infants and children, the elderly, and pregnant women, as well as ophthalmic and injectable products"
- Prioritized enforcement will also fall within other categories such as
  - "Products with reports of injury that, after evaluation, raise potential safety concerns,"
  - "Products that contain or purport to contain ingredients associated with potentially significant safety concerns,"
  - Products intended to be used for the prevention or treatment of serious and/or lifethreatening diseases or conditions."

VENABLE LLP

FDA Issues New Medical Device Software Guidance

FDA has also now issued a new Guidance on their "Policy for Device Software Functions and Mobile Medical Applications"

1. This outlines several examples of software functions that may or may not be considered medical device functions and thus, regulated as such. Follows the 21st Century Cures Act amendments, added 21 USC 360j(o), which designates software functions that are **not** considered medical devices.
2. In addition, FDA published a Digital Health Policy Navigator that helps determine whether a software function would be the focus of FDA oversight: https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-policy-navigator.
3. For example, FDA will exercise enforcement discretion with respect to "Software functions that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care professional."

VENABLE LLP

FDA Safety and Landmark Advancements Act (FDASLA)

- U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee sent to the full Senate for consideration
  - Mandatory Product Listing Proposal
    - Would require listing of all dietary supplement products and ingredients with FDA
    - Well-intentioned but with several unintended consequences
  - Proposed companion language: ""[t]he introduction or delivery for introduction into interstate commerce of any product marketed as a dietary supplement that does not meet the definition of a dietary supplement under section 201(ff)" is a prohibited act.
    - Implications for NAC and CBD
    - Impact on good and bad actors
- FDA's existing authority to take action

VENABLE LLP

Cosmetics Legislation Updates

1. Personal Care Safety Act S. 2100 was introduced by Dianne Feinstein again in 2021
    - Would require registration of cosmetics manufacturers; disclose ingredient list for all cosmetic products in the registered facility.
    - FDA must annually conduct a safety review of at least five cosmetics ingredients or nonfunctional constituents and, if appropriate, issue a final finding on the safety of that ingredient or constituent.
    - The FDA must also implement regulations for good cosmetics manufacturing practices.
2. Modernization of Cosmetics Regulation Act of 2022 is within FDASLA proposal. This includes many of the same provisions as the PCSA, but would not require annual 5-ingredient review, and would not require registration fees or ban PFAS in cosmetics.

VENABLE LLP

Litigation Targets From 2022 and Looking Toward 2023

1. Flavor and color claims
   - All-natural
   - "No artificial" colors, flavors, ingredients, etc.
   - Always keep in mind when characterizing flavor that FDA views all colors as artificial
2. Per-serving/per-capsule challenges (such as vitamin C, for instance) regarding the potency of serving/capsule sizes
3. SF claim substantiation challenges (e.g., for vitamins)

VENABLE LLP

Prop 65 Updates

1. New safe harbor warning approved for glyphosate - September 8
2. Prop 65 Notices continue
    - Heavy Metals in dietary supplements and seafood
    - Acrylamide
    - Lead
    - Titanium dioxide and phthalates (in cosmetics)
3. PFOA/PFOS (and PFNA) also likely to continue as targets

VENABLE LLP

Questions?

Todd A. Harrison
Partner and Co-Chair
+1 202.344.4724
taharrison@Venable.com

Claudia A. Lewis
Partner and Co-Chair
+1 202.344.4359
calewis@Venable.com

VENABLE LLP

VENABLE LLP