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Distilling FSMA

Alcohol Beverages and the FDA

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LEHRMAN BEVERAGE LAW

Charles M. Breen
John D. Messinger

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Presenters

Charles Breen

Mr. Breen joined EAS after a distinguished career at the FDA working in areas such as HACCP and LACF and BSE prohibited materials in the dairy. He led the field and headquarters professionals in developing and implementing surveillance and compliance programs, as well as development of the initial FSMA training implementation. His attention to detail has garnered him an FDA Award of Merit, Outstanding Achievement and five Commissioner Special Citations.

John Messinger

Mr. Messinger is a Senior Attorney at Lehrman Beverage Law, PLLC. John received his J.D. from American University, Washington College of Law, and joined the firm as an attorney in 2009. He assists wine, beer and spirits companies with labeling, formulation, licensing, advertising, taxation, product development and other federal and state compliance matters.

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What is an "Alcohol Beverage?"

- Federal Alcohol Act – All beverages containing 0.5% or more alcohol by volume (ABV) any time during their manufacture.
- Food & Drug Act – Any article of food or drink for humans or animals.
- Congress did not concern itself with the redundancy; the agencies did and signed agreement to divide tasks.

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Types of Alcohol Beverages

- **Distilled Spirits:** "Ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whisky … including all dilutions and mixtures thereof" (27 CFR 5.11). Does not include a blend of wine and spirits if ≤ 24% ABV and more than 50% wine on a proof gallon basis.
- **Wine:**
  - IRC (26 USC 5381) – "Natural wine is the product of the juice or must of sound, ripe grapes or other sound, ripe fruit …"
  - FAA Act (27 CFR 4.10) – As defined at 26 USC 5381-5392, and agricultural wines, vermouth, cider, sake, etc. containing between 7% and 24% ABV.
- **Beer:**
  - IRC (26 USC 5052(a)) – a) fermented beverage of b) 0.5% alc/vol or more, produced or brewed from c) malt or a substitute.
  - FAA Act (27 CFR 7.10) – a) alcoholic fermentation, b) in potable water, c) of malted barley and d) with hops.

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FDA Responsibility

- Manufacturing – Must register with FDA. All alcohol beverages (ABs) must be made in compliance with FDA current Good Manufacturing Practices (cGMPs) regulations in 21 CFR 117 subpart B.
- cGMPs primarily address sanitation, cleanliness, employee hygiene, unadulterated ingredients.
- ABs exempt from Preventive Controls, Foreign Supplier Verification, and LACF regulations.

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TTB Responsibility

- Jurisdiction over all domestic production of ABs (even for products under FDA's labeling jurisdiction).
- Collecting excise taxes.
- Formulations and lab analysis.
- Trade practice enforcement (e.g. tied house).
- For 7%+ ABV wine, all distilled spirits, and all malt beverages: Certificate of Label Approvals (COLAs), Marketing/Advertising/Social Media.

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TTB – FDA MOU

- FDA responsible for labeling of ABs:
  - Cider under 7% ABV
  - Wine under 7% ABV
  - Sugar based hard seltzers under 7% ABV
  - Kombucha NEVER at or above 0.5% ABV during production, at time of bottling, or after bottling
  - Beers that are made from substitutes for malted barley (e.g., sorghum, rice, or wheat) and beers made without hops.
- ***NOT INCLUDING*** distilled spirits, wine with ≥ 7% ABV, or most beers, including saké.

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FDA Labeling Requirements

- Fair Packaging and Labeling Act regulations
  - Such as:
    - –Nutrition Panel
    - –Ingredients
    - –Allergens

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TTB Labeling Requirements

- Brand Name
- Class/Type or Statement of Composition
- Alcohol Content Statement (percent alcohol by volume)
- Net Contents
- Bottler's Name and Address
- Government Warning
- Commodity Specific Information

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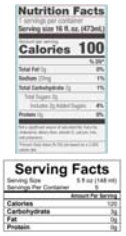
TTB vs. FDA Labeling

- Nutrition Facts vs. Serving Facts/Average Analysis
- Health-Related Statements
- Ingredient Statements: Mandatory vs. Optional
- Principal Display Panel vs. Brand Label
- Allergen Labeling, Juice Content, Type/WONF



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FDA Responsibility

- Non-GRAS food additives and colors require FDA approval for use.
- GRAS ingredients must be generally recognized as safe in the intended AB.
- FDA provides laboratory support and conducts health hazard evaluations on substances at TTB request.

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TTB Formulations

- Basically, a recipe for the product (ingredients and production process).
- A prerequisite for label approval (only if required).
- What TTB is looking for:
  - Colors, Flavors
  - GRAS Ingredients (Generally Recognized as Safe)
  - Restricted and Limited Ingredients
  - Non-Traditional Processes
- Most of the burden to prove whether an ingredient is GRAS is on the applicant.

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