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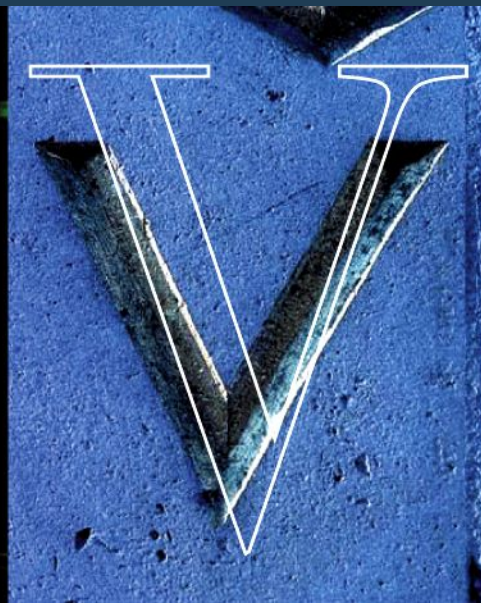
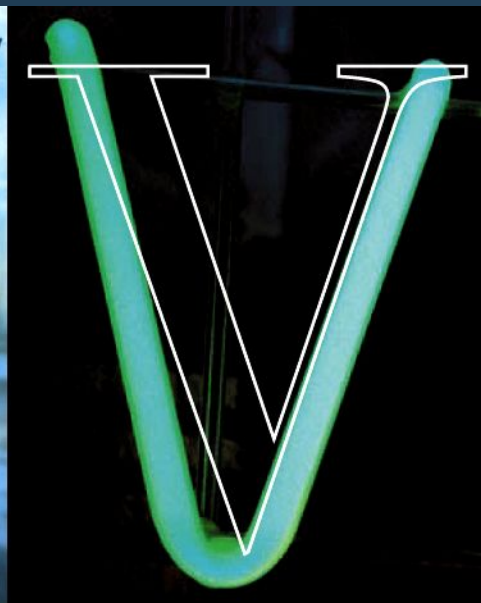
Townhall: What Regulators and Other Attorneys Will Not Tell You About FDA, FTC and Class Action Lawsuits

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Agenda

- Current Enforcement Trends
- What is a Claim?
- Substantiation
- Hot Topic Claims
- FDA Warning Letters
- California's Proposition 65



Current Enforcement Trends

- FDA Enforcing *Draft* Guidance as Final Guidance
- FDA Warning Letters
 - Current Good Manufacturing Practices
 - Claims: Inflammation, Blood Sugar Levels
- Uptick in Substantiation Challenges
 - California DA



FDA Draft Guidance Activity

New Dietary Ingredients



- Draft Guidance (July 2011): Synthetic copies of botanical constituents are not dietary ingredients permitted for use in supplements.
- **Dimethylamylamine (DMAA or geranium extract)**
 - April 2012: FDA issued 10 warning letters
 - May 2012: Numerous class action lawsuits filed. Claims include:
 - Synthetic Source of DMAA (not a dietary ingredient)
 - Failure to file NDI notification.
 - Failure to establish product safety.
 - January 2013: USPLabs set aside \$2M to settle DMAA lawsuits to “*avoid the cost and risk of further trial.*”
 - June 2013: FDA seized 1,500 cases of supplements containing DMAA from GNC warehouse.

NOTE: CLRA letters have been issued re less-publicized NDIs.



FDA Draft Guidance Activity

Medical Foods

- Revised Draft Guidance (September 2013): Add “extra-statutory restrictions.” For example, medical foods may be marketed only for diseases and conditions the dietary management of which cannot be achieved by ***modification of the normal diet alone***.
 - Lists Diabetes (Types 1 and 2)
- **Metagenics Warning Letter**: The agency is “not aware of any distinctive nutritional requirement or unique nutritional need for patients with Type 2 Diabetes that cannot be met through dietary modification alone.”



FDA Warning Letters

cGMP Compliance

■ **Statistics:**

- 30+ Issued Since January 1, 2013.
- Inspectors **cite 70%** of Dietary Supplement Firms
 - 444 out of 626 inspections for cGMPS resulted in issuance of Form 483 (2010-2012)
 - 116 dietary supplement firms received “official action” (WL) in 2012. [[Anywhere for 2 to 58 violations cited.]]

■ **Obligation of Private Label Distributor to:**

- Confirm they receive what they order from contract manufacturer or labeler.
 - “[T]o the extent that [company] manufactures dietary supplements on your behalf as a contract manufacturer, that your firm releases for distribution under your firm’s name, your firm has an obligation to know what and how manufacturing activities are performed so that you can make decisions related to whether your dietary supplement products conform to established specifications and whether to approve and release the products for distribution.” FDA, Warning Letter, Lumina Health Products, Inc. (Aug. 1, 2013).
- Perform finished batch identity testing.
 - “You are required to verify that either every finished dietary supplement batch or a subset of the finished dietary supplement batches that you identify through a sound statistical sampling plan meet the finished product specifications for identity, purity, strength and composition.” FDA, Warning Letter, Precise Nutrition International, Inc. (July 11, 2013).



FDA Warning Letters

Claims

- Blood Sugar
 - FDA issued 9 WLs in June-July 2013 against companies marketing dietary supplements allegedly claiming to mitigate, treat, cure or prevent diabetes and related complications.
 - How far is too far? Below are cited “disease” claims:
 - “Naturally control and maintain you blood glucose levels.”
 - “Sugar Balancer”
 - “Lower blood sugar & A1c levels”
 - “[Product] not only helps to bring down the blood sugar level, it also helps repair β cells and restore the function of pancreas.”
 - “Lessened total insulin needed.”
 - “It has been proven by a research . . . to have similar effects to medicines used in diabetes treatment.”
 - “NEW – Advanced Nutraceutical Stops This Silent Killer Before It Destroy[s] You . . . And those You Love!”



FDA Warning Letters

Claims

■ Inflammation

– 2013 Examples:

- “Holm Oak (an ingredient in your product) ... [a]nti-inflammatory and antibiotic properties.” [[Brower 9/9/2013]]
- “It supports...the body’s natural anti-inflammatory response.” [[Y.S. Health 8/29/13]]
- “Grape seed extract contains polyphenols which have been shown in clinical studies to exhibit anti-inflammatory activity. ... For example in a study conducted by the University of Rovira, in Spain, researchers concluded that Grape Seed Extract demonstrates a potential health benefit in inflammatory conditions.... ” [[Nature Cast Products 7/15/13]]
- “[Product] is an all-natural herbal supplement known to reduce pain and inflammation...” [[Entrenet 5/8/2013]]



What is a Claim?

- A claim is an explicit or implicit statement that a product has a certain benefit.
 - Express and implied claims are held to the same standard.
 - Claims are identified by assessing the “net impression” conveyed by all elements of an advertisement or label, including text, product name and depictions.
 - Includes statements made in testimonials.

- Types of claims include:
 - Overall Health and Wellbeing
 - Structure/Function Claims
 - Health Claims
 - Nutrient Content Claims
 - Comparative Claims



Claim Substantiation



- FTC and FDA require “competent and reliable scientific evidence” to substantiate all claims used in advertising and structure/function claims used on labels.
- “Competent and reliable scientific evidence” =
 - Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area,
 - That have been conducted and evaluated in an objective manner by persons qualified to do so,
 - Using procedures generally accepted in the profession to yield accurate and reliable results.



Claim Substantiation



- Factors Affecting Required Levels of Substantiation:
 - Type of product
 - Type of claim
 - Benefits of truthful claim
 - Consequences of false claim
 - What qualified experts in field believe is reasonable
 - Is specific level of support stated or suggested in the claim?



Claim Substantiation



■ Acceptable Scientific Evidence:

- Well-controlled, double-blind studies are likely to be given more weight than non-blind studies;
- Longer-term studies are better than short-term studies;
- Study's result should be statistically significant;
- Nature and quality of the written report is important;
- Studies published in reputable peer-reviewed scientific journals are looked upon with favor;
- Studies not published in peer-reviewed journals may be used to substantiate claims if they would be considered properly designed and controlled by experts in the field.



Claim Substantiation



■ Scientific Evidence Must Be Relevant

- Evidence must be relevant to specific claim
- Study endpoints must match claim
 - Ensure that you understand meaning of claim to determine what endpoints are relevant.
- Consider: dose, dosage form, route of administration, formulation, total length of exposure, frequency of exposure, study population
- Foreign Research
 - Note that differences between populations, such as differences in diet, general health, or patterns of use, could confound results.



Claim Substantiation



Issues with Other Types of Scientific Evidence

- FDA View: Alone, items listed below generally will not substantiate claims:
 - Animal Studies– best is based on data from studies in appropriate animal models, on data that have been reproduced in different laboratories, and on data that give a statistically significant dose-response relationship.
 - In vitro Studies– best is based on data that have been reproduced in different laboratories.
 - Testimonial/Anecdotal Evidence– “honest opinion” not enough
 - Meta-analysis– may identify relevant reports, which may provide substantiation
 - Product monographs– may provide background information useful to understand relationship between substance and claimed effect



What Does Your Study *Really* Show?

- Taking leaps in logic or “connecting the dots” is one of the most frequent mistakes companies make
 - Your study shows that the product does A
 - You know that A is associated with B
 - Therefore you claim that the product does B

Beware of These Areas:

- Website reviews posted by customers
- Social Media (e.g., Facebook pages)
- Guarantees



Regulatory Update: Prop. 65

- **AB 227:** CA Assembly voted to amend Prop. 65 by allowing *certain* small business owners 14 days to fix an alleged violation of the warning requirements. Applies to private citizen enforcement. (May 2013). Does not apply to food and dietary supplement companies.
- **ERC continues submission of Prop 65 Notice of Violations involving Lead.**
- ***Environmental Law Foundation v. Beech-Nut Nutrition Corp (Baby Food Trial)***
 - Rare: Only 9 out of 3,000 have gone to trial since 1986.
 - Judgment Entered for Defendants August 7, 2013: Each product is below the regulatory “safe harbor” exposure level; no Prop 65 warning required.
 - Appellate action? CA Supreme Court could, for the first time in many years, decide questions of law regarding Prop. 65.
- **BPA Delisted (April 2013)**





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