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United States Dietary Supplement Regulatory Update

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Agenda

- Food and Drug Administration
- Federal Trade Commission
- California's Proposition 65
- Class Actions

Regulatory Update: FDA
Warning Letters

- GMP violations
  - Over 35 issued from January 1st to early December 2013
    - **Popular Violations**:
      - Failed to establish specifications (21 CFR 111.70). [approx. 30]
      - Failed to qualify a component supplier by establishing reliability of the supplier's COA (21 CFR 111.75(a)(2)). [approx. 13]
  - 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.

Regulatory Update: FDA

Warning Letters

Private Label Distributors

- "A firm that contracts with other firms to conduct certain dietary supplement manufacturing, packaging, and labeling operations for it is responsible for ensuring that the product is not adulterated for failure to comply with dietary supplement CGMP requirements, regardless of who actually performs the dietary supplement CGMP operations."
- 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).

Regulatory Update: FDA

Warning Letters

Inflammation Claims

- 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]

Regulatory Update: FDA

Warning Letters

- Blood Sugar Claims
  - 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!"

Regulatory Update: FDA

Consent Decrees

- November 2011: First time FDA took legal action against a large dietary supplement company for cGMP violations.
  - Primary Violation: ***Substituting ingredients and products without noting the changes on final product labels.***
- 3 Dietary Supplement Companies Ordered to Stop Manufacturing for cGMP violations since FDA's first action (2 in 2013).
  - Ex. Titan Medical (February 2013).
    - 3 Inspections (2010-2012) revealed failure to comply with dietary supplement cGMPs.
      - Failed to verify that a subset of finished supplement batches met product specifications.
      - Failed to adequately confirm identity of supplement components.
    - 9 inspections (2001-2013) revealed failure to comply with drug cGMPs.

Regulatory Update: FDA

Product Seizure

- June 2013: FDA seize 1,500 cases of supplements containing DMAA from GNC warehouse.
  - Products: Jack3d, Oxylite Pro
  - July 3, 2013: USPlabs (distributor) voluntarily destroyed DMAA-containing products at Texas facility (est. value: $8 M).
  - April 2012: 11 Warning Letters issued stating that DMAA is unsafe and not a dietary ingredient (no NDI submitted).
- October 2012: Dietary supplements claiming to prevent or treat disease seized from Confidence, Inc.
  - Products: Dr. Brain, pH Balance, Fe-Mon-9, Glucosamine Plus, and Prostate-7.
  - Disease Claims: Treat or cure specific diseases or conditions, such as senile dementia, brain atrophy, atherosclerosis, kidney dysfunction, gangrene, depression, osteoarthritis, dysuria and several types of cancer (*e.g.*, lung, cervix and prostate).

Regulatory Update: FDA

- What is the purpose of the Dietary Supplement Health and Education Act (DSHEA)?
  - Disease Claim Defined
    - Metabolic Syndrome?
    - Cholesterol?
    - Inflammation?

FDA's broad interpretation thwarts purpose of DSHEA.

Regulatory Update: FTC

- HOT: health-related advertising
  - weight loss
  - cognitive claims
  - disease treatment and prevention
  - up-to claims
- Significant Decisions
  - *POM Wonderful* (Jan. 2013) – 2 randomized and controlled human controlled trials for disease claims.
  - *Jason Pharm.* (Sept. 2012) – 1 study for weight loss claims.
- .Com Disclosure Guide Revised (Mar. 2013)
- Amended COPPA rule took effect July 1, 2013.
  - New round of enforcement likely for food companies that use websites, apps, or other online programs.
- Environmental Seals, Certifications & recent enforcement

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).
- **Governor seeking reforms (May 2013).**
  - End frivolous "shake-down" lawsuits
  - Improve how public warned
- **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.
  - July 2013: Court ruled in favor of the defendant companies and held that any alleged exposures to lead in fruit juice and baby food products did not exceed the "safe harbor" level triggering a requirement to warn under Proposition 65. In doing so, the court ruled on a key issue that had not previously been litigated in any other Proposition 65 trial involving lead -- whether or not the "safe harbor" limit for lead exposure should be calculated on the basis of average exposure or maximum daily exposure.
- **BPA Delisted (April 2013)**

Regulatory Update: Class Actions

Natural Claims Are Everywhere…

And so are the lawsuits.

Regulatory Update: Class Actions

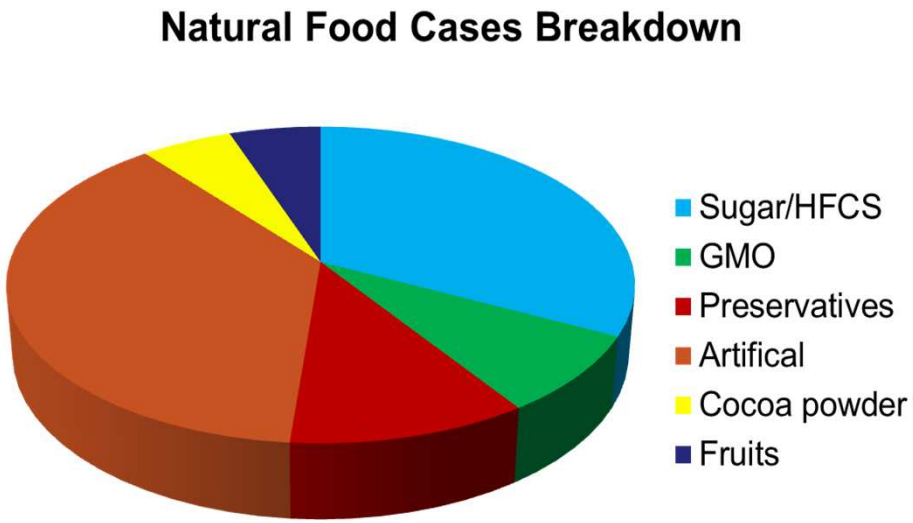
- *Complaint Claims, generally*

  - Fraud
  - Breach of Warranty
  - CA ("Food Court") Consumer Protection Statutes: Unfair Competition Law, False Advertising Law, and Consumer Legal Remedies Act

Regulatory Update: Class Actions

All-Natural Claims Litigation

- ***Marketing***: "100% Natural," "Pure," "All-Natural," "Natural," "Made with real fruit and other all natural ingredients," etc.



Regulatory Update: Class Actions

Other Hot Topics

- Weight Loss Products
- Joint Products
- Male Sexual Performance Products

Weight Loss Products

- *Problematic Claims:*
  - "Eat all you want and still lose weight.“
  - Specific areas of fat loss.
  - Specific amount of weight loss in a short period of time.
    - Ex. “Clinically proven to result in an average weight loss of 30.5 lbs. in just 6 months.”
  - Requires no diet or exercise.
  - “Up to” claims.

Regulatory Update: Class Actions

- **Joint Products**
  - Target Glucosamine Chondroitin
  - Plaintiff's Expert One of the Primary Authors of the GAIT Study
    - Declaration critical of Glucosamine Hcl but not necessarily of Sulfate
  - Products intended to treat osteoarthritis
  - Cartilage claims
  - Maximum and Clinical Strength

Regulatory Update: Class Actions

- **Male Performance Products**
  - At least 10 active cases
  - Testosterone boosters
  - Boost testosterone by 47%
  - Increase muscle mass and strength gains in men
  - Exaggerate Testimonials
  - Clinical Tests Misrepresented
    - Claim an active ingredient "increases human growth hormone factors by 140% when taken 30 minutes before training." However, when tested against placebo, the active ingredient only outperformed the placebo by 1%.

Regulatory Update: Class Actions

Should companies spend the money on studies?

- Double-edged sword.

  - Conduct studies for hero products that have a good ingredient substantiation.

Fighting Back Against Plaintiff Class Actions

Arbitration Agreements

Class Action Waivers

- *AT&T Mobility LLC v. Concepcion* (SCOTUS)
  - Federal law favors arbitration agreements, even in consumer contracts (case-by-case analysis).
- Will it work?
  - Unconscionability determination varies from court to court.
- Include in Terms and Conditions at POS.
  - Label vs. Label Insert
- Benefits:
  - If court then compels arbitration, company's potential exposure and legal fees are dramatically reduced.
  - Language may deter class action entirely.

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