Substantiation and Risk Management For Dietary Supplement Claims

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Claims and Consequences

• What are label claims?
• What are the requirements for labeling and advertising of dietary supplements?
• What effects can promotional claims have on a consumer healthcare company?
• What can happen if you make an inaccurate or non-complaint label claims?
Sources of Risk

- FDA
- FTC
- State Attorneys General
- Private and/or class action litigation
- Ingredient suppliers
- Colleagues at your company
- Competitors
- Customers
What kinds of claims are there?

- Health claims overseen in 3 ways
  1. NLEA, 1990
  2. FDAMA, 1997
  3. Qualified Health Claims
- Nutrient content claims
- Structure/Function claims
Qualified Health Claims

- Calcium and osteoporosis
- Folic acid and neural tube defects
- Stanols/sterols and cardiovascular disease
- Selenium and certain cancers
- Omega 3 fatty acids and heart disease
- Antioxidant vitamins and certain cancers
- Calcium and colorectal cancer
- Phosphatidylserine and cognitive dysfunction and dementia
- Others
Nutrient Content Claims

• NLEA permits the use of label claims that characterize the level of a nutrient in a food.
  • Includes terms such as *free*, *high*, and *low*
• Food would have to meet the nutritional criteria for a particular nutrient content claim (e.g., “low”) or carry a disclosure statement that it does not qualify for the claim (e.g., “not a low sodium food”).
• Most nutrient content claim regulations apply only to those nutrients that have an established Daily Value (DV)
  • Healthy is an implied nutrient content claim.
  • Percentage claims for dietary supplements are another category of nutrient content claims.
Structure/Function Claims

  • Preamble
  • Discusses what are and are not disease claims
• Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide
• Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading.
• FDA guidance is modeled on, and complements, FTC guidance.
Structure/Function Claims

- S/F claims may
  - describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body.
  - characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function.
- General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient.
- Nutrient deficiency disease claims describe a benefit related to a nutrient deficiency disease.
  - E.g., vitamin C and scurvy.
  - Must say how widespread the disease is in the United States.
  - Not pre-approved by FDA, but the manufacturer must
    - have substantiation that the claim is truthful and not misleading
    - submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim.
- Must carry the disclaimer
The Disclaimer

“This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.”
Where did the permissibility of S/F claims come from?

• From the definition of a drug.
• Section 201(g)(1) of the FFDCA defines drugs as:
  A. Articles in the U.S. Pharmacopeia, Homeopathic Pharmacopeia of the U.S., or National formulary, or any supplements to them and
  B. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals and
  C. Articles (other than food) intended to affect the structure or any function of the body of humans or other animals and
  D. Articles intended for use as components of any article specified above
Disease claims vs Structure-Function Claims

- If you make a disease claim for your dietary supplement, you cause the product to become a drug that is misbranded, considered an unapproved new drug, and no longer a dietary supplement.
- Common (not abnormal) health conditions are not diseases.
  - E.g., stage of life conditions such as menopausal hot flashes, teenage acne
- Many old and present OTC drug claims OK as S/F claims.
  - Minor pain relief, calming and relaxing
- References to published articles are generally OK but not on label.
- No implied disease claims and no disease markers.
  - Organ dysfunction, relief of disease signs/sx, references to drug classes, augments or replaces drug therapy, adverse effects of dz, augments body’s response to dz
Disease claims, examples

- Prevents cancer, or nausea during chemo.
- Reduces arthritis pain or stiffness
- Shrinks an enlarged prostate
- Controls blood sugar in diabetics
- Antidepressant
- Relieves headache or migraine
- Antifungal, antibiotic or antiseptic
Acceptable S/F claims

• Promotes a healthy urinary tract
• Helps maintain cardiovascular function
• Promotes healthy digestion
• For relief of occasional constipation
• Helps maintain healthy intestinal flora
• Supports a healthy immune system
• Reduces everyday stress and frustration.
• Helps maintain regularity
• Supports normal joint function
• Helps maintain healthy lung function
• Helps maintain cholesterol already in the normal range
Cannot mention drug classes

- Antibiotic
- Antiviral
- Diuretic
- Antidepressant
- Anti-inflammatory
- Analgesic
- Beta-blocker
- Et cetera
S/F Claims Notification

• 21 CFR Sec. 101.93
• 30 day post-market claims notification and DSHEA label disclaimer create an exemption from the requirement that a health claim be approved by FDA
• FDA reviews and provides courtesy letter if claim is a disease claim
FDA has been expanding its definition of disease

- Inflammation is a case-in-point. Warning letters have been issued for all of the following statements:
  - “Safe and effective alternative for the management of minor pain and discomfort relating to typical inflammatory conditions.”
  - “Reduces pain-causing enzymes.”
  - “Support joint health and soothe aches from over-exertion of everyday activities.”
  - “Prevent immune-mediated inflammatory skin disorders (inflammatory acne, eczema and most dermatitis reactions).”
  - “Decreases enzymes that cause inflammation.”
  - “Reduces inflammation.”
  - “Anti-inflammatory”
  - “Treats arthritic joint inflammation”
  - “Eases rheumatism, gout and joint swelling.”
  - “Reduces inflammation at joints.”
  - “Anti-inflammatory in rheumatic diseases.”
When in doubt, act “normal”

• The most carefully crafted inflammation claims tend to say things like:
  • “helps to maintain normal inflammatory process”
  • “helps promote normal inflammatory response”
• DSHEA Section 6 “describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being by consumption of a nutrient or dietary ingredient.”
FTC presents a different kind of risk

• As applied to dietary supplements, the FDA has primary responsibility for claims on product labeling.
• The FTC has primary responsibility for claims in advertising.
FTC’s approach

• Advertising for any product, including dietary supplements, must be truthful, not misleading, and substantiated.

• FTC’s approach to supplement advertising is best illustrated by its Enforcement Policy Statement on Food.

• FTC gives deference to an FDA determination of whether there is adequate support for a health claim.

• All parties who participate directly or indirectly in the marketing of dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.
Competent and reliable scientific evidence

- Tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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.
- No pre-established formula as to how many or what type of studies are needed to substantiate a claim.
Issues to consider

1. The meaning of the claim(s) being made
2. The relationship of the evidence to the claim
3. The quality of the evidence
4. The totality of the evidence
Hierarchy of Evidence

- Randomized, placebo-controlled double-blind clinical trial published in peer reviewed medical journal
- Single-blind, published clinical trial
- Open label, published clinical trial
- Unpublished clinical data, Anecdotal reports
- Animal study
- In vitro study
Another way to look at it

⭐⭐⭐ Reliable and relatively consistent scientific data showing a substantial health benefit.

⭐⭐ Contradictory, insufficient, or preliminary studies suggesting a health benefit or minimal health benefit.

⭐ For an herb, supported by traditional use but minimal or no scientific evidence. For a supplement, little scientific support and/or minimal health benefit.
FTC Claims Guidance: Identifying Claims and Interpreting Ad Meaning

- Identifying express and implied claims
- When to Disclose Qualifying Information
- Clear and Prominent Disclosure
FTC Claims Guidance: Substantiating Claims

- Ads that Refer to a Specific Level of Support
- The Amount and Type of Evidence
- The Quality of the Evidence
- The Totality of the Evidence
- The Relevance to the Evidence to the Specific Claim
FTC Claims Guidance: 

Other Issues

• Claims based on Consumer Testimonials and Expert Endorsements
• Claims based on Traditional
• Use of the DSHEA Disclaimer in Advertising
• Third Party Literature
Internet and Social Media

• Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media.
  • This includes social media sites like Facebook and Twitter.

• Customer endorsements, testimonials and comments posted to a firm’s social media site constitute claims.

• Change comments option to rating system.
Bayer Prevails Over FTC In Closely Watched Case Involving Claims For Probiotics

• FTC argued that Bayer violated the consent decree based on claims that its Phillips’ Colon Health product can “defend against” occasional constipation, diarrhea, and gas and bloating.
  • Alleged that this implied claims that it prevents, treats and cures constipation, diarrhea, and gas and bloating.
• Bayer voluminous evidence on the effectiveness of the ingredients.
• FTC and its experts argued that only randomized, controlled studies on the exact same combination of the exact same strains of probiotics can be “competent and reliable scientific evidence” for those claims.
  • that combining ingredients could impact their efficacy, and studies on one probiotic strain cannot be used to substantiate claims for other strains.
• U.S. District Court in New Jersey decided against the FTC and did not hold Bayer Corp in contempt for violating its 2007 FTC consent decree.
Litigation Trends

1. False and Misleading claims
2. “All-natural” claims
3. Dangerous, Failure to Warn
4. Product Liability
5. “Healthy” claims
6. Nutrient Content Claims
7. Prop 65
8. Weight Loss Claims

Source: Crawford E. The Tan Sheet, 2013, interview with Justin Prochnow
FDA Criminal Investigations

1) Rhode Island Businessman Pleads Guilty to Marketing and Selling Unapproved Remedies for Cancer Mitigation and Treatment, Tax Evasion

2) Owner Of Dietary Supplement Company Sentenced To 40 Months In Prison For Multimillion-Dollar Scheme To Adulterate Dietary Supplements.

3) Florida and Louisiana Residents Charged In Multi-State Scheme to Distribute Illegal and Mislabeled Diet Pills

4) Seller of "Miracle Mineral Solution" Convicted for Marketing Toxic Chemical as a Miracle Cure

5) Entrepreneur Sentenced, Ordered to Forfeit $650,000 for Distributing Anabolic Steroids as Dietary Supplements

6) Owner of Harrisburg Diet Supplement Business Charged with Selling Misbranded Drugs

7) Maker of Erectile Dysfunction Products Sentenced To Nine Years In Prison For Misbranding And Selling Drugs As "All-natural" Herbal Supplements
FTC claims substantiation actions (Some headlines from 2014)

• Judge Issues Order to Jail Two Dietary Supplement Sellers for Contempt
• FTC Approves Final Order Settling Charges that “BrainStrong Adult” Supplement Marketers Made Deceptive Memory Improvement Claims
• FTC Obtains $2.2 Million Judgment against Supplement Marketer that Made Phony Claims for Treating and Preventing Diabetes
• Companies Pitching Genetically Customized Nutritional Supplements Will Drop Misleading Disease Claims
• FTC Settlement Bans Marketer Behind ‘Fat Burner’ Diet Pills from Manufacturing, Marketing Weight-Loss Products
• Cactus Juice Marketers to Pay $3.5 Million in Refunds to Consumers for Deceptive Claims that Their Product Treats Diseases
• Marketers of ‘Fat Burning’ and ‘Calorie Blocking’ Diet Pills to Pay $500,000 for Making Deceptive Weight Loss Claims
• Green Coffee Bean Manufacturer Settles FTC Charges of Pushing its Product Based on Results of “Seriously Flawed” Weight-Loss Study
• FDA issued this warning letter to Windmill Health Products, alleging that the company made disease claims on supplement product labels and the company website
New York Attorney General Actions

- Feb 2015: NYAG sent cease-and-desist letters to four major US retail chains informing them that they must stop selling store brands of herbal dietary supplements that were found problematic in DNA barcoding tests.
- Alleged that only 21% of the store-brand herbal supplements contained DNA from the plants listed on the products’ labels.
- Science and industry experts in almost unanimous agreement that the NYAG study was not based on adequate science and its actions were premature.
- Companies were forced to spend a lot of money to jump through a lot of hoops. Some, like GNC, capitulated to the demand for inappropriate testing.
NYAG goes after Devil’s Claw

• Sent cease-and-desist letters to 13 companies informing them that their products contain a “less desirable” species of Devil’s claw.
• Incorrect conclusion based on a too-narrow interpretation of botanical classifications.
• The two species are similarly effective, have similar chemical profiles, are regarded by medical authorities as being interchangeable, and have been marketed so since at least the 1980s.
• Q: Why is the NYAG going after a relatively low-selling herb (annual sales in the U.S. estimated to be between $250-500K)?
Reducing Risk

• RTFM
• Follow your own SOPs
• Don’t lie, don’t exaggerate.
• Know the science. Have documentation.
• Tell the truth, if it’s allowed.
• Better yet, make no claims, or make fewer claims.
• Always have multiple sets of eyes vet the claims before pre-market submission to FDA,
  • including Marketing, Regulatory, Scientific Affairs, (and Legal dept, when necessary)
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