2014 Weight Management Technologies Seminar

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Regulatory Landscape: Law and the Players

• Regulatory agencies and jurisdiction:
  – FDA: Food Label and Labeling
  – FTC: Food Advertising

• Other “players”
  – Class action plaintiffs
  – State Attorneys General
  – National Advertising Division (NAD)
  – Center for Science in the Public Interest (CSPI)
Food / Drug Continuum

Food

Dietary Guidance

Nutrient Content Claims

Health claims/ qualified health claims

Structure or Function Claims

Drug

Disease Claims
“Food” Regulatory Boxes

Nutrient Content
Health
Structure Function
Drug
Cosmetic
Qualified Health
Dietary Supplement
Dietary Guidance
Nutrient Content Claims

- Defined:

  Nutrient Content: A claim that expressly or by implication characterizes the level of a nutrient of the type required in nutrition labeling

  21 CFR 101.13(b)

- FFDCA deems a food misbranded for bearing a nutrient content claim unless FDA has issued a regulation authorizing the claim and the claim is made consistent with the claim (FFDCA 403(r)(1)(A))
Nutrient Content Claims: Defined Terms

- “High,” “Rich in,” “Excellent source of,”
- “Good source of,” “Contains,” “Provides,”
- “High potency,”
- “Free,” “No,” “Without,” “Trivial source of,” “Negligible source of” “Dietarily insignificant source of,”
- “Low,” “Very low,”
- “Lite,” “Light,”
- “Reduced,” “Fewer,” “Lower,” “Less”
- Health, healthy, healthily . . .
Relative Claims
21 C.F.R. 101.13(j)

- Nutrient content claims may compare the level of a nutrient in one food with that of another food such as “light,” “reduced,” “less,” “fewer,” “more,” and many others
  - The claim must identify the percent decrease/increase from the reference food
    - 50 percent less fat than butter
    - 1/3 fewer calories than whole milk
    - 10% more fiber than regular crackers
  - The claim must disclose the level of the nutrient in the product and the reference food (e.g., regular butter 12 g fat our product 9 g fat)
  - Relative claims for decreased levels of a nutrient are prohibited if reference food qualifies for a “low” claim
  - Relative claims require significant label real estate!
Structure/Function Claims

• Definition: statement that relates the role of a nutrient (substance) on the structure or function of the body
  – Tip: Statement like you would find in a medical text book could be s/f claim
Constructing Lawful Structure/Function Claim

- Focus on whether the structure/function claim involves a healthy person or normal bodily function versus an unhealthy person or abnormal bodily function.
- Focus on how closely the claim is associated with a specific disease condition.
### Structure/Function Claims

<table>
<thead>
<tr>
<th>Acceptable</th>
<th>Not Acceptable</th>
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<tr>
<td>Maintains healthy cholesterol for people with normal cholesterol</td>
<td>Lowers cholesterol</td>
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<tr>
<td>Supports memory</td>
<td>Reduces memory loss in elderly people</td>
</tr>
<tr>
<td>Provides energy</td>
<td>Natural stimulant to prevent drowsiness</td>
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Advertising Law in 3 Easy Steps

• What claims are conveyed by the advertisement?
  – Express and implied claims; “net impression”
  – Unintended claims account for most false advertising cases
  – Omission of material facts

• Can advertiser support claims conveyed?
  – False advertising arises from unsupported objective claim

• Level of proof required? The amount suggested by the claim
Level of Proof Dictated by the Claim

• Health and efficacy claims generally require a high level of proof - - “competent and reliable scientific evidence”
  – Consists of: tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been evaluated and conducted and evaluated in an objective manner by qualified persons, using procedures generally accepted in the profession to yield accurate and reliable results.
  – Bias toward consensus experts in the field
  – Points to the importance of evaluating studies in the context of the wider body of scientific evidence
Weight Loss: FTC Aggressive Enforcement

- Novel ingredients and false weight loss claims
  - Green coffee bean
  - Acacia berry
- Targets – “burn fat,” “increase metabolism,” “suppress appetite”
- Enforcement includes refunds to consumers
  - Past 10 years, 82 cases, $107M restitution
Weight Loss – Relevance of FTC Enforcement?

• Cautionary tale – “amid an ongoing obesity epidemic” per FTC
• “Red Flag” category of claims
• Prospect for “spill-over” to “conventional” or “nutritional” foods?
Weight Loss: Clinical Support (flaws/strengths)

• At least one adequate and well-controlled human clinical study
• Avoid using company employees
• “Calculated” weight loss based on estimated calorie reduction generally not a viable approach
• Study population should match target advertising audience
• Self-reporting “diary” approach lacks reliability
• Nutrition counseling for only the “test group” can skew results
• Optimal to use advertised product in clinical study
Weight Loss: Framing the Claim Properly

- “Results may vary” insufficient
- Claim should focus on the typical (“average”) results found in a study; not outliers
- If atypical results highlighted, must also disclose the expected weight loss that most people should expect
- Avoid “up to” claims
- “Long term” weight loss based on two-year minimum follow-up with study participants
- Mention of other “lifestyle factors” is important
- Ensure that the studies match the claims made
“Gluten-Free” - - Legal Definition

• A gluten-free claim means that the food does not contain
  – A gluten-containing grain, which is defined to include wheat, rye, barley, or a crossbred hybrid of those grains
  – An ingredient that is derived from a gluten-containing grain that has not been processed to remove gluten; or
  – An ingredient derived from a gluten-containing grain that has been processed to remove gluten but still contains 20 parts per million (ppm) or more of gluten
  – If the presence of gluten is unavoidable, the food must still contain less than 20 ppm of gluten
“Gluten-Free”: Permitted Synonyms

• Other like claims include:
  – “No gluten”
  – “Free of gluten”
  – “Without gluten”

• Such terms are also subject to “gluten-free” requirements

• Unqualified “gluten-free” claim allowed for foods that are inherently gluten-free
  – Contrast to foods that are inherently fat free (“carrot, a naturally fat free food”)
Alternatives to “Gluten Free”

- Regulation only defines “gluten-free”
- Absence of gluten claims permitted
  - FDA would allow: “Made with no gluten-containing ingredients” or “not made with gluten-containing ingredients”
  - Statements are not assumed to mean that the food is “gluten-free”
- Advisory statement about cross-contact from equipment allowed
  - “Made in a facility that also processes wheat” on foods labeled gluten-free is permitted BUT the food must qualify for a gluten-free claim (i.e., less than 20 ppm)
Marketing to Gluten-Intolerant Consumers

- Possible that reduced gluten levels (not below 20 ppm) may be useful to segments of population even though not authorized by FDA’s new rule.
- Ingredient statements presented in a context that is unlikely to mislead may be defensible
  - Example: “Made with Rice Flour”
- Quantitative statements may also be defensible
  - Example: Contains 120 ppm gluten
    - Would require testing to verify amount
    - Is the amount a meaningful level to a distinct population?
    - Nutrition/health issue so may be a benefit in working with someone knowledgeable in field
Marketing to Gluten-Intolerant Consumers

• An inherently difficult proposition
  – Must avoid confusion where sufferer of celiac disease mistakenly consumes lower gluten food that is above 20 ppm
  – Should have a basis for the dietary benefit for a food at a reduced gluten level that exceeds 20 ppm
  – Possible avenues to pursue this type of approach but carries risk that is dictated by:
    • Claims used and contextual information provided
    • The risk that consumers will conclude a food is gluten-free when it is not
    • The amount of gluten above 20 ppm is not well-controlled due to deficiencies or limits of Standard Operating Procedures
Marketing to Gluten-Intolerant Consumers

- “Low-gluten diet” or “Gluten-Friendly”?
- Use of a disclaimer?
- Execution?
Satiety

• Claim drives level of substantiation
• Examples:
  – Taste that satisfies
  – Provides appetite control
  – Helps hold you over until the next meal
  – You won’t need to snack between meals
  – Keeps you feeling full for four hours
  – Keeps you feeling fuller 2x longer than competitor’s product
Satiety: Constructing a Robust Study

• Ideal to conduct study on product to be marketed
• Comparable product with comparable levels of key nutrients/ingredients defensible
• How does the study measure-up against other studies in the field?
Dynamic Regulatory Environment

What lies ahead...
FTC Lowers Boom on Nutrition and Health Claims

• String of consent orders

• Common themes
  – Don’t make claims related to immunity beyond “helps support the immune system”
  – Big and small companies both targets
  – Painfully exacting assessment of science that sets very high bar

• Consequences of “getting it wrong” – consent order and severe restrictions on future conduct
FTC Developments and Consequences

• Level of science and rigor of scrutiny of ingredient-based benefit claims has risen significantly at state and federal level
  – Whole grain, fiber, probiotics, DHA, and other well-studied nutrients that confer positive nutrition/health benefit could be target of FTC scrutiny depending on claims made

• Two or more well-designed studies on product or primary ingredient prudent

• Claim tied to limits of science

• Ensure science relied upon consistent with wider body of scientific evidence
(Proposed) Declaration of Added Sugars

• Definition: “sugars that are either added during the processing of foods or are packaged as such”

• Exemption: if product contains less than 1 g added sugars per serving if no claims are made about sweeteners, sugars, added sugars, or sugar alcohol
  – Would need to add “Not a significant source of added sugars”

• FDA views declaration of added sugars as necessary to provide consumers information to implement dietary recommendations to reduce intake of calories from added sugars and consume nutrient-dense foods

• Agency recognizes the lack of reliable analytical methods to distinguish added sugars
  – Amount must be verified through maintenance and review of records

• No DRV proposed for added sugars

• Can FDA defend this sweeping change??
FDA Menu Labeling: Focus on Calories

• Mandatory calorie labeling on menus and complete in-store information will be required
• Significant expense and change in how nutrition information is now provided
• Implications for foodservice providers
  – Frequency of changes in ingredients that effect nutrition
  – Opportunity to support (or frustrate) your customers
Key Take-Away Messages

• How you frame your claim is critical
  – For FDA, dictates what legal requirements apply
  – Determines the level of support is required

• Assemble your team early: Scientific, Regulatory/Legal and Marketing
  – Will the clinical study hypothesis advance the underlying business objectives?

• Robust study design essential, with valid end-points identified at the outset

• Frame clear, concise claims
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