FTC & FDA Claims Dietary Supplement Substantiation Requirements

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The opinions expressed are the speaker’s and not his company’s.
The FDA has primary responsibility for claim on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale.

The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogs, and similar direct marketing materials.

Agencies coordinate on dietary supplement claim policy issues.
Both the FDA and FTC expect (and legally require) that all claims regarding dietary supplements must meet both of these basic requirements:

- Truthful and not misleading; and
- Adequately substantiated at the time the claim is made

No premarket review of claims by either Agency; a company is expected to have substantiation in its files.
Claims must be supported with "competent and reliable scientific evidence," defined as:

- 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.

Concurs with FTC that claims must be supported with "competent and reliable scientific evidence."

Guidance Documents:
Amount & Type of Substantiation

**FTC**
- A number of factors determine the appropriate amount and type of substantiation including:
  - Type of product
  - Type of claim
  - Benefits of a truthful claim and the cost/feasibility of developing substantiation for the claim
  - Consequences of a false claim
  - Amount of substantiation the experts in the field believe is reasonable
  - Quality of evidence
  - Totality of evidence

**FDA**
- In determining whether the substantiation standard has been met, the following should be considered:
  - Meaning of the claim being made
  - Relationship of evidence to the claim
  - Quality of the evidence
  - Totality of the evidence
Health Claims

- Per FTC, “the absence of an FDA determination that a health claim is scientifically valid will be a significant factor in the Commission assessment of the adequacy of substantiation for the claims.”

- FTC regards the “significant scientific agreement” standard to be the principal guide to what experts in the field would consider reasonable substantiation for an unqualified health claim; therefore, likely that FTC will reach same conclusion on issue as FDA.

- Where advertiser makes a specific claim that product can treat, cure, prevent, or reduce the risk of disease, FTC will require such claims to be approved by the FDA.

- If a specific claim would not be permitted by FDA in labeling, the FTC will not permit it in advertising.
Other Health Related Claims

- Per FTC Guidance, there is not a fixed formula for the number of studies required to substantiate a claim or for more specific parameters like sample size and study duration.

- However, consent orders in some recent FTC cases have required that the company not make the claims at issue again, unless it has competent and reliable scientific evidence to support the claims and has defined such evidence to consist of:
  - at least two adequate and well-controlled human clinical studies on the product, or of an essentially equivalent product
  - conducted by different researchers, independently of each other,
  - that conform to acceptable designs and protocols and
  - whose results, when considered in light of the entire body of relevant and reliable scientific evidence, are sufficient to substantiate that the representation is true
Arguably.......No.

The requirement noted was for the specific claims at issue

Given the type of claims made by the companies in the recent FTC cases, one can postulate experts would generally not consider one study to be adequate to support the claims made.

Significantly in the orders, the FTC requires for all other claims made by the company that the company possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. This is the current standard and no additional specificity is provided.
Recent Cases

- **The Dannon Company** (Activia Yogurt, Consent Order January 2011)
- **Nestlé Healthcare Nutrition** (Nestle Boost Essentials Drink, Consent Order January 2011)
- **Ivoate Health Science** (various weight-loss, immune, and allergy supplements, Final Judgment & Order July 2010)
- **POM Wonderful** (POM Wonderful pomegranate juice and POMx pills, complaint filed September 2010)
Dannon – Activa Claims

- One daily serving of Activia® relieves irregularity (Per FTC: 3 servings needed to obtain benefit)
- “Clinically proven to help regulate your digestive system in two weeks”
- Helps with “slow intestinal transit time”
- “Clinically proven to help strengthen your body’s defenses” (which together with visuals per FTC: conveyed that it helped people avoid catching colds or the flu)
Nestlé -Kids Essentials® Claims

- “prevention of upper respiratory tract infection,” “protects against cold and flu,” “reduces absence from school” and “reduces duration of acute diarrhea in children up to 13”

- Per FTC: some good evidence, but claims went beyond what the studies showed
Per FTC: ads claimed Cold MD and Germ MD prevented colds or flu and were “clinically proven” to do so.
lovate- nanoSLIM and Accelis Claims

- Caused weight loss and “clinically proven” to do so
- Using nanoSLIM - “Lose 32 lbs FAST”

- Per FTC: claimed Accelis was scientifically proven to increase the body’s metabolism
Per FTC:

- “Clinically proven” claims about benefits for heart disease, prostate cancer, erectile dysfunction
- No blinding or control in prostate cancer study
- No benefit beyond placebo in erectile dysfunction study
- Many studies for heart disease showed no benefit
Quality of evidence (FTC Guidance 2001)

- A study that is carefully controlled, with blinding of subjects and researchers, is likely to yield more reliable results
- A study of longer duration can provide better evidence that the claimed effect will persist and resolve potential safety questions
- Evidence of a dose-response relationship
- Statistical significance of findings
- Results translate into a meaningful benefit for consumers
Study Considerations (cont’d)

- **Quality of evidence (FDA Guidance 2008)**
  - **Adequacy and clarity of design**
    - Research objective and study methodology clear and appropriate
    - Duration sufficient
    - Confounders identified/assessed/controlled
    - Subject attrition assessed/explained/reasonable
  - **Population studied**
    - Large enough to provide sufficient statistical power to detect a significant effect
    - Representative of target population
    - Inclusion/exclusion criteria clearly state and appropriate
    - Recruitment procedures minimized selection bias
    - Subjects randomized and randomization successful in producing similar control and intervention groups
Quality of evidence (FDA Guidance 2008)

Assessment of intervention/exposure and outcomes

- Analytical methodology and quality control procedures to assess dietary intake adequate
- Dietary supplement serving size well defined and appropriately measured
- Background diets to which dietary supplement added adequately described, measured and suitable
- Form, dosage and setting of intervention representative of the way the product will normally be used
- Concurrent changes in diet or health-related behavior (weight loss, alcohol intake, etc.) present during study that could account for outcome identified and assessed and/or control
- Study outcomes well defined and appropriately measured
- Efforts made to detect harmful and beneficial effects
Quality of evidence (FDA Guidance 2008)

Data Analysis and Assessment
- Appropriate statistical analysis applied to data
- Statistical significance interpreted appropriately
- Relative and absolute effects distinguished.

Peer Review
- Publication in peer-reviewed journal not required, but does give some level of assurance that qualified experts have reviewed the research and found it to be of sufficient quality and validity to merit publication
- Publication itself does not necessarily mean that research is competent and evidence adequate to substantiate a claim
Questions