

## Successfully Navigating Legal Requirements for Health-Related Claims

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# Health Claims -- Eligibility

- Decreased dietary level
  - If claim is based on decreased dietary level in conventional food, substance must be a nutrient required to be listed in nutrition labeling
- Other than decreased dietary level
  - If claim is based on presence at other than decreased level, substance must be used in conventional food for a traditional food purpose – taste, aroma, nutritive value or other technical effect recognized by FDA
  - Nutritive value – having a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients or providing energy.
  - Nutritive value versus therapeutic effect
- “Conventional food”
  - Means food other than dietary supplements and includes “functional food” (FDA has not defined functional food)

# Health Claims -- Eligibility

- Other than decreased dietary level
  - Must be safe at the level use in the food and also the level expected to be consumed when the health claim is issued (e.g., dietary fiber and cancer).
  - Concern may result in FDA limiting claim to certain types of food
- If substance not covered by a food additive or GRAS regulation
  - Burden on petitioner to submit data necessary to support safety determination
  - FDA may require a GRAS notification or food additive petition
  - FDA has discretion to accept self-determined GRAS position

# Health Claims -- Evidence

- FDA considers totality of evidence supporting a claim
- Greatest weight -- well-designed human studies (FDA requirements for institutional review and informed consent).
- Nonclinical laboratory studies should be conducted in accordance with FDA's good lab practice requirements.
- Analytical epidemiological studies should include reliable controls or may be used when scientific conditions or ethical considerations preclude more controlled studies.
- Overriding principle – whether there are consistent results from different types of well-conducted human studies by different investigators in different populations.

# Health Claims -- Evidence

- U.S. Supreme Court Central Hudson test
  - Last prong – government must use least restrictive means of regulating commercial speech necessary to advance the goal of protecting the public interest
- Pearson Decision
  - If adequate scientific evidence to support a health claim, FDA must consider whether a disclaimer would communicate the level of support
  - No definition of adequate scientific evidence except to suggest FDA can deny claim if:
    - scientific support for the claim is outweighed by evidence against, or
    - a disclaimer cannot correct potential consumer confusion re level of support

# Health Claim Petition–Time Period

- Petitions not denied or accepted for filing within 100 days are deemed denied (unless time extended)
- Petitions accepted by FDA for filing but not acted on within 90 days are deemed denied (unless time extended)
- If FDA issues proposed rules within 90 days of accepting petitions, FDA must complete the rulemaking within 540 days of receipt. Otherwise, FDA must report to Congress on the reason for the delay.
- Failure of FDA to act on a petition within the designated time period is a final agency action subject to court review.

# FDAMA -- Authoritative Statement

- Notification to FDA at least 120 days prior to using claim
- Can be used after 120 days unless FDA publishes a regulation prohibiting the claim
- Exact wording must be submitted
- Basis for the claim (balanced view of scientific literature)
- What federal scientific bodies may be used?
  - National Academy of Sciences (and subdivisions)
  - National Institutes of Health
  - Centers for Disease Control and Prevention
  - Surgeon General
  - Food and Nutrition Service
  - Food Safety and Inspection Service
  - Agricultural Research Service

# Health Claims in Advertising--FTC

- No unqualified health claim unless SSA
- Claims not approved by FDA are not automatically prohibited in ads, but are subject to strict scrutiny
- Claims not approved by FDA may be permitted if qualifications clearly convey degree of scientific support and evidence in support is not inconsistent with a larger body of evidence
- Health claims for foods “disqualified” by FDA permitted if adequate qualification re the significance of the ingredient
- Generally, health claims permitted in ads only if the ingredient is present at a level sufficient to confer a meaningful health benefit

# Qualified Health Claims -- Update

- Industry concerns -- no qualified health claim petitions filed in 2007 for conventional foods
- Congressional concerns – 12/2007 appropriations bill urged FDA not to use those funds to review qualified health claims for conventional foods or to permit such claims through enforcement discretion until Government Accountability Office report
- Senators Durbin and Kennedy; Representatives DeLauro and Waxman wrote to FDA in March asking FDA to clarify its plans re qualified health claims for conventional foods
- Coalition of medical, health and consumer groups supports FDA ban on reviewing qualified health claims for conventional foods

# Qualified Health Claim Examples

- Green Tea and Reduced Risk of Cancer – “Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer.”
- Tomatoes and Prostate, Ovarian, Gastric and Pancreatic Cancers – “Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.”

# Nutrient Content Claims



- **Antioxidant nutrient content claims**

- established Reference Daily Intake (RDI)
- scientifically recognized antioxidant activity
  - **absorption from the gastrointestinal tract;**
  - **participation in physiological/biochemical/cellular processes;**
  - **inactivate free radicals/prevent free radical-initiated chemical reactions**

- name the specific nutrient(s) either in the claim or by a symbol linking to a statement on same panel
- "high/rich in/excellent source of" (at least 20% of the RDI)
- "good source/contains/provides" (10 to 19% of the RDI)
- "more/fortified/enriched/added/extra/plus" (at least 10% more of RDI per RACC than an appropriate reference food)

- **Vitamin and mineral content claims**

- statement re the % RDI of a vitamin or mineral may be made with authorizing regulation

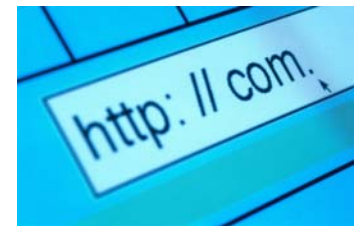


# Nutrient Content Claims

- **Advertising – FTC Enforcement Policy**
  - Urges advertisers to follow FDA regulations
  - Synonyms of FDA-defined terms permitted if not misleading (“packed with” as equivalent to “high in”)
  - Broader latitude in general

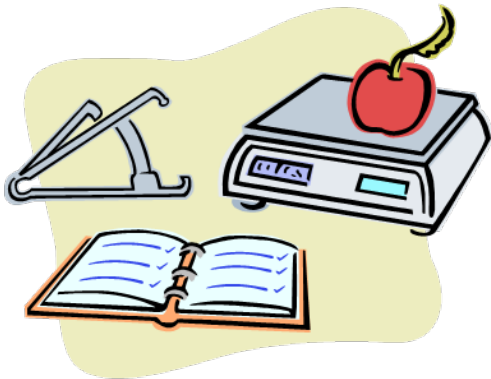
# Labeling and Advertising

- **Labeling vs. Advertising – Web sites may be considered labeling**
  - Web site is an extension of the label; subject to labeling requirements
  - 2001 -- FDA Warning Letter – “The container labels for your ... products ...bear your internet website address... We have concluded that the **labeling** found on your internet sites causes your products to be in violation” of the FD&C Act and regulations.
  - “May help the body fight cancer”
  - Significant enforcement in this area



# Quantitative Information

- **Statement re amount of a nutrient permitted if it "does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect" (e.g., "80 calories")**
- **Additional terms may result in a nutrient content claim (e.g., "only 80 calories")**



# Quantitative Information

- **Antioxidant information**
  - can describe nutrients without RDIs
  - claim must be true and not characterize the level of the nutrient
  - quantity of an antioxidant per serving permitted
  
- **Quantitative information can be declared for any substance unless false or misleading**



# Structure/Function Claims

- Describe the effect of food/nutrient on the structure/function of the body
- Cannot suggest that the food is useful in diagnosis, cure, treatment, prevention or mitigation of a disease or health-related condition.
- Substantiation – at least competent and reliable scientific evidence that supports the truthfulness of the claim
- Notice to FDA and disclaimer (“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease”) are not required for conventional food
- FDA position -- structure/function claims for conventional food must be based on nutritive value (not a requirement for dietary supplement structure/function claims).
  - Defined nutritive value in the context of health claims
  - Means having a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

# Structure/Function Claims

## General criteria:

- May not suggest that the product has an effect on a disease
- May not refer to a characteristic sign or symptom of a disease
- May refer to signs and/or symptoms of natural states if not uncommon or can cause significant harm if left untreated
- May cite an article that refers to a disease in its title if the labeling taken as a whole does not imply a disease prevention or treatment claim
- May not use pictures, vignettes, symbols, or other means to suggest the presence of a disease condition
- May not suggest usefulness in conjunction with regular drug therapy, or in preventing/treating adverse events associated with a disease if the adverse events are also disease conditions.
- Catch all: may not use a claim that “otherwise” suggests a disease

# Warning Letters



- FDA Warning Letters re Web site claims
- October 2005 to 29 companies producing, marketing or distributing cherry, blueberry, pomegranate and apple products
- Similar claims, including that the fruit helps fight cancer, heart disease and diabetes, provides relief for arthritis, gout, migraine headaches and fibromyalgia, treats Alzheimer's and macular degeneration.
- "Claims cause products to be drugs"



# Dietary Guidance Statements

- Refer to general dietary patterns, practices, and recommendations that promote health
- May mention a substance or a disease/health-related condition, but not both
- Example: “Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases”
- No prior approval from FDA is required before use in labeling, but statements must be truthful and not misleading

# 2005 Dietary Guidelines



- 1/ 2005: Dept of Health and Human Services (HHS) and Dept of Agriculture (USDA) issued the 2005 edition of the Dietary Guidelines for Americans
- Provide science-based advice to promote health and reduce risk for major chronic diseases through diet and physical activity.
- Federal dietary guidance for the public must be consistent with Dietary Guidelines, and Federal agencies carrying out any Federal food, nutrition, or health program must promote the Dietary Guidelines.
- Authoritative statements in the “Executive Summary” or “Key Recommendations” sections of the Dietary Guidelines may be the basis of a Food and Drug Administration Modernization Act (FDAMA) notification to FDA re specific health or nutrient content claims.
- Can use nutrient content claim in conjunction with a Dietary Guidelines statement:
  - **“High in Potassium. The 2005 Dietary Guidelines recommend diets high in potassium to help prevent hypertension or help manage blood pressure.”**