Label Claims

Vincent de Jesus
Office of Nutrition, Labeling, and Dietary Supplements
FDA:CFSAN
Audience Poll

The science behind each label claim made on a conventional food or dietary supplement package is reviewed and the language is approved by FDA.

True or False
Nutrition Labeling and Education Act (NLEA) of 1990

• Amended the Federal Food And Drug Cosmetic Act (1938)

• Rationale:
  – Assist consumer in maintaining healthy dietary practices
  – Provide level playing-field for claims
  – Encourage innovations in food products
    • Marketing incentive
NLEA

- Provided for
  - Mandatory Nutrition Facts label
  - Voluntary nutrition claims
    - Nutrient content claims when defined by FDA
    - Health claims when authorized by FDA
Answer to Audience Poll

Low Fat

Make at least half your grains whole grains

Healthy!

FALSE

Good source of vitamin C

5 grams of carbohydrate per serving

Calcium helps build strong bones
Types of Label Claims

• Health Claims
  – Authorized (Significant Scientific Agreement, SSA)
  – Qualified Health Claim
  – FDA Modernization Act of 1997 (FDAMA)

• Nutrient Content Claims
  – FDAMA

• Structure/Function Claims
Health Claims

• “Health Claim” is an express or implied statement in food labeling about the relationship of a food substance to a disease or health-related condition.

• Not just “any claim about health”

• Require pre-approval by FDA

• Can be used on conventional foods and dietary supplements
Subject of a Health Claim

- Causal relationship between a substance and a disease or health-related condition for the general U.S. population or subpopulation (e.g., women, elderly)

- Ability to reduce the risk of disease
  - **Not** treat, prevent, cure or mitigate
    - Drug
Elements of Health Claims

Substance
A specific food (tomato) or component of food (lycopene), whether in conventional food or dietary supplement form

Disease or Health-Related Condition
Damage to an organ, part, structure, or system of the body such that it does not function properly (e.g. CHD), or a state of health leading to such dysfunctioning (e.g. hypertension)
1990 Health Claim Standard

NLEA permits authorization...only when it has determined, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement (SSA), among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Selected Authorized Health Claims

- Calcium, Vitamin D and osteoporosis
- Dietary fat and cancer
- Dietary saturated fat and cholesterol and heart disease
- Fiber containing grain products, fruits and vegetables (certain foods) and cancer
- Fruits, vegetables and grain products (soluble fiber) and heart disease
- Non-cariogenic sweeteners and dental caries
- Soy protein and heart disease
- Plant stanols /sterols ester and heart disease
Qualified Health Claims

• Qualified Health Claims are based on scientific evidence that is credible but that does not meet the SSA standard

• Include qualifying language to prevent consumers from being misled about the level of support for the claim

• Considered under FDA’s exercise of enforcement discretion (not authorized by regulation)
Example of QHC Language

- Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease (Oct. 2004)

“Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.”
QHC Examples

• QHCs: Heart Disease
  – Omega 3 fatty acids (EPA/DHA)
  – Monounsaturated fatty acids from olive oil
  – Unsaturated fatty acids from corn oil
  – Walnuts
  – Nuts
  – B vitamins and vascular disease

• QHCs: Cancer
  – Calcium and colon/rectal cancer
  – Green tea and breast/prostate cancer
  – Selenium and site-specific cancers
  – Antioxidant vitamins and certain cancers
  – Tomato and prostate cancer

FDA qualified health claims: http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006877.htm
Nutrient Content Claims

– Describe the level of a nutrient or a dietary substance
– Terms include free, high, low
– Comparative claims more, reduced, lite
– Healthy
– Simple amount or percent claims

Information on Nutrient Content Claims:
http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm
Nutrient Content Claims Disclosure Statement

• Disclosure Statement
  
  – A statement that calls the consumer's attention to one or more nutrients in the food that may increase the risk of a disease or health-related condition that is diet related. “See nutrition information for ____ content.”
  
  – Required if NCC is on a food which exceeds prescribed levels of fat, saturated fat, cholesterol, or sodium
Disclosure Levels

- Total Fat: 13.0 grams
- Saturated Fat: 4.0 grams
- Cholesterol: 60 milligrams
- Sodium: 480 milligrams

*per RACC, per labeled serving, or, for foods with small serving sizes, per 50g. (Different levels apply to main dish and meal products)
Express Claims

• Direct statement about the level (or range) of a nutrient in the food

  – Absolute
    • Describes the level of a nutrient in a product

  – Relative
    • Compares the level of a nutrient in a food to that of another food
Express: Absolute Claims

• Free: depends on nutrient
  – Fat: < 0.5g per RACC and labeled serving
  – Sodium: < 5mg per RACC and labeled serving

• Low: depends on nutrient
  – Fat: ≤ 3g per RACC
  – Sodium: ≤ 140mg per RACC

• Good source: 10%-19% of Daily Value per RACC

• Excellent source: ≥ 20% of Daily Value per RACC
Express: Relative Claims

• Reduced (lower, fewer):
  – at least 25% reduction for the nutrient per RACC compared to an appropriate reference food*

• More (added, extra):
  – at least 10% more of the Daily Value for a nutrient per RACC than an appropriate reference food*

*A reference food must be a food or group of foods that are representative of the same type as the food bearing the claim. The type of food used as a reference food must be identified on the label as part of the accompanying information.
Implied Claims

• Claims that suggest that a nutrient is present or absent in a certain amount:
  – “contains no oil” → fat free

• Claims that suggest a food may be useful in maintaining healthy dietary practices:
  – “healthy, contains 3g of fat”

• Equivalence claims:
  – “as much vitamin C as an 8oz glass of orange juice”
Healthy

- "Healthy" and any derivative, e.g. "health" or "healthful," are implied NCCs that suggest that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices.

- Nutrient requirements for total fat, saturated fat, sodium, cholesterol, and beneficial nutrients (vitamin A, vitamin C, iron, calcium, protein, or fiber)
Criteria for Use of “Healthy”

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Fat</td>
<td>3 g or less/RACC (low)</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>1 g or less/RACC &amp; 15% or less calories (low)</td>
</tr>
<tr>
<td>Sodium*</td>
<td>480 mg or less/RACC &amp; per labeled serving</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>60 mg or less/RACC &amp; per labeled serving</td>
</tr>
<tr>
<td>Beneficial Nutrients</td>
<td>At least 10% RDI or DRV per RACC for one or more of vitamins A, C, iron, calcium, protein, or fiber</td>
</tr>
</tbody>
</table>

*Seafood/game meats; main dishes different requirements
Amount and Percentage Statements

• Claims are permitted about the amount of a nutrient, provided such claims do not implicitly characterize the level of nutrient in the product
  – “100 calories”
  – “5 grams of carbohydrates”

• No authorization needed for statement that describes the percentage of a vitamin or mineral in a food in relation to DV
  – “60% of the DV for vitamin C”

• Statements are still nutrient content claims
FDAMA

• Food and Drug Administration Modernization Act (FDAMA) of 1997: amended FFDCA to allow claims based on authoritative statements from appropriate scientific bodies
  – Provides an alternative notification process to the petition process for nutrition claims

• Intent: to expedite the process by which the scientific basis for such claims is established
  – Example: Potassium and reduced risk of high blood pressure and stroke

Information on FDAMA claims:
http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006874.htm
Structure/Function Claims

• Describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans
  – “Calcium builds strong bones”
  – “Lycopene promotes prostate health”

• May characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function
  – “Antioxidants maintain cell integrity”
  – “Fiber maintains bowel regularity”

Information on structure/function claims:
http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006881.htm
Structure/Function Requirements

• Not pre-approved by agency

• All claims must be truthful and not misleading

• Supplement manufacturers must notify FDA of claim within 30 days after marketing

• Dietary supplements must include a disclaimer that states FDA has not evaluated the claim and the supplement is not intended to "diagnose, treat, cure or prevent any disease"

• Foods do not need disclaimer statement

Information on structure/function claims:
http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006881.htm
Thank you!