Health Claims on Food & Supplements: Fact or Fiction?

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Understanding Health Claims on Foods and Supplements

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Project D-FEND: Diet, Food, Exercise, and Nutrition during social distancing. A collaboration between the University of Arkansas System Division of Agriculture's Center for Human Nutrition and the University of Arkansas Exercise is Medicine Program. The University of Arkansas System Division of Agriculture is an equal opportunity/affirmative action institution.
Objectives

• Understand the food label

• Define health claims

• Understand how health claims on foods and supplements are regulated

• Understand how to determine if claims are fact or fiction
Food and Drug Administration

• Agency of the US Department of Health and Human Services

• Responsible for protecting and promoting public health through the regulation and supervision of **food safety**, tobacco products, **dietary supplements**, prescription and over-the-counter medications, vaccines, veterinary products
The Nutrition Labeling and Education Act of 1990

- **Gives the FDA explicit authority** to require nutrition labeling on most food packages and specified the nutrients to be listed in the nutrition label.

- **Requires that nutrients be presented in the context of the daily diet**
  - Specified that serving sizes should represent “an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food.”

- **Required standard definitions to be developed** that characterized the level of nutrients and required that FDA provide for approved health claims.

- **Permitted the FDA to add or delete nutrients** based on a determination that such a change would “assist consumers in maintaining healthy dietary practices.”

- The NLEA **pertains only to those labels of food products regulated by FDA**, which has label authority over the majority of foods.
  - However, meat and poultry product labels are under the authority of FSIS in the USDA, and alcoholic beverage product labels are under the authority of the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury, formerly the Bureau of Alcohol, Tobacco and Firearms.
Main Goals of the Nutrition Label

The purpose of FDA’s proposal was threefold:

1. To clear up confusion that had surrounded nutrition labeling for years,

2. to help consumers choose healthier diets, and

3. To give food companies an incentive to improve the nutritional qualities of their products
Check the Ingredient List

- Foods with more than one ingredient must have an ingredient list on the label.
- Ingredients are listed in descending order by weight. Those in the largest amounts are listed first.
Specific Ingredient List Guidelines

• **List ingredients in descending order, sorted by weight.** The ingredient with most weight is listed first, and the ingredient with the least weight is listed last.

• **List the common or usual name for ingredients** unless there is a regulation that provides for a different term. For instance, use the term "sugar" instead of the scientific name "sucrose." Example - INGREDIENTS: Apples, Sugar, Water, and Spices

• **Trace ingredients do not need to be listed if a substance is an incidental additive and has no function or technical effect in the finished product.** Sulfites are considered to be incidental only if present at less than 10 ppm.

• **Chemical preservatives that are added to a food, must be included using both the common or usual name of the preservative and the function of the preservative by including terms, such as "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor," or "to promote color retention."** Example - INGREDIENTS: Dried Bananas, Sugar, Salt, and Ascorbic Acid to Promote Color Retention.

• **Spices may be declared in ingredient lists by using either specific common or usual names or by using the declarations "spices," "flavor," or "natural flavor," or "artificial flavor."** Example - INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, Natural Flavor and Artificial Flavor

http://www.fda.gov/Food/
Ingredients: Whole Grain Corn, Whole Grain Oats, Sugar, Whole Grain Barley, Whole Grain Rice, Whole Grain Wheat, Corn Starch, Brown Sugar Syrup, Corn Bran, Salt, Trisodium Phosphate, Canola and/or Rice Bran Oil, Distilled Monoglycerides, Color Added. Vitamin E (Mixed Tocopherols) Added to Preserve Freshness. Vitamins and Minerals: Calcium Carbonate, Zinc and Iron (Mineral Nutrients)Vitamin E (Tocopheryl Acetate)a B Vitamin (Niacinamide)Vitamin C (Sodium Ascorbate)a B Vitamin (Calcium Pantothenate)Vitamin B6 (Pyridoxine Hydrochloride)Vitamin B2 (Riboflavin)Vitamin B1 (Thiamin Mononitrate)a B Vitamin (Folic Acid)Vitamin A (Palmitate)Vitamin B12, Vitamin D.
Health claims – What are they?
Types of Label Claims?

• Health Claims

• Nutrient Content Claim

• Structure/Function Claims

Health Claims - EFSA (European Food Standards Agency)
https://www.youtube.com/watch?v=3zNL21gjwuo
Health Claims

• A claim authorized by the US Food and Drug Administration (FDA) that **must be supported by credible scientific evidence** regarding a relationship between a substance (specific food or food component) and a disease or health-related condition.

• Can be authorized or qualified.
Health Claims

A health claim is defined as any claim that states, suggests, or implies that a relationship exists between a food category, a food, or one of its constituents and health.

**Authorized Health Claim**
- Describes a health claim that has been reviewed by the FDA and approved for use.
- This means that you can make an authorized health claim on your precut without needing the FDA to approve.
- There must be significant scientific agreement (SSA), which means the science supporting the health claim is unlikely to change.

https://www.fdareader.com/blog/2018/12/17/authorized-health-claims
Authorized health claims that meet the SSA standard

- Calcium, vitamin D, and osteoporosis
- Dietary lipids (fat) and cancer
- Dietary saturated fat and cholesterol and risk of coronary heart disease
- Dietary non-cariogenic carbohydrate sweeteners and dental caries
- Folic acid and neural tube defects
- Fiber-containing grain products, fruits, and vegetables, and cancer
- Fruits and vegetables and cancer
- Fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease
- Sodium and hypertension
- Soluble fiber from certain foods and risk of coronary heart disease
- Soy protein and risk of coronary heart disease
- Stanols/sterols and risk of coronary heart disease

https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard
Qualified Health Claim

- Qualified Health Claim is a statement approved by the FDA for use on food labels that has strict wording requirements.

- When there is emerging evidence between a food and the reduced risk of a disease or health condition, but not enough for the FDA to issue an Authorized Health Claim, the FDA may approve a "Qualified Health Claim”

**Example of a Qualified Health Claim:**

- "Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive."

https://www.fdareader.com/blog/2018/12/17/qualified-health-claims
Qualified Health Claims

• Atopic dermatitis
• Cancer (e.g. green tea, tomatoes)
• Cardiovascular disease (e.g. nuts, omega-3 fatty acids)
• Cognitive function (e.g. phosphatidylserine)
• Diabetes (e.g. whole grains)
• Hypertension (e.g. EPA, DHA)
• Peanut allergy
• Urinary tract infection (e.g. cranberry juice)
Requirements for a health claim

• Health claims cannot be made about the diagnosis, cure, mitigation or treatment of diseases (this is a drug claim).

• They must be complete, truthful and not misleading.

• Certain foods may be disqualified from health claims based on nutrient levels that are deemed unhealthy. Health claims must be associated with a risk or health related condition for which the US population or a subgroup (i.e. the elderly) is at risk.

• The substance that is the subject of the health claim must have a taste, aroma or nutrient value when consumed at the levels used to justify the claim.
Example: Health Claim

Calcium and Osteoporosis

• **Claim:** A diet adequate in calcium may help reduce the risk for osteoporosis, a degenerative bone disease.

• **Requirements:** At least 200 milligrams calcium, no more phosphorus than calcium per serving, and calcium must be in a form that can be readily absorbed by the body.

[http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064919.htm](http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064919.htm)
Example: Plant Sterols

*Plant Sterol/stanol esters and Risk of Coronary Heart Disease

(21 CFR 101.83)

At least 0.65 g plant sterol esters per RACC of spreads and salad dressings, or
At least 1.7 g plant stanol esters per RACC of spreads, salad dressings, snack bars, and dietary supplements.
Low saturated fat,
Low cholesterol, and
Spreads and salad dressings that exceed 13

Required terms:
"May" or "might" reduce the risk of CHD
"Heart disease" or "coronary heart disease"
"Plant sterol esters" or "plant stanol esters"; except "vegetable oil" may replace the term "plant" if vegetable oil is the sole source of the sterol/stanol ester
Claim specifies plant stero/stanol esters are part of a diet low in saturated fat and cholesterol.
Claim does not attribute any degree of

(1) Foods containing at least 0.65 gram per of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies ___ grams of vegetable oil sterol esters.

(2) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064919.htm
Nutrient Content Claims

• Nutrient content claims describe the level of a nutrient in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and lite.
Nutrient Content Claims, cont’d

• Most nutrient content claims regulations apply only to those nutrients or dietary substances that have an established Daily Value (DV).

• The manufacturer must ensure that the exact wording of the claim, including specific descriptive words, is consistent with FDA’s regulations, as only authorized nutrient content claims are permitted for use.
<table>
<thead>
<tr>
<th>Nutritional Claim</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calorie free</td>
<td>Less than 5 calories</td>
</tr>
<tr>
<td>Sugar free</td>
<td>Less than 0.5 grams of sugar</td>
</tr>
<tr>
<td>Fat</td>
<td></td>
</tr>
<tr>
<td>Fat free</td>
<td>Less than 0.5 grams of fat</td>
</tr>
<tr>
<td>Low fat</td>
<td>3 grams of fat or less</td>
</tr>
<tr>
<td>Reduced fat or less fat</td>
<td>At least 25 percent less fat than the regular product</td>
</tr>
<tr>
<td>Low in saturated fat</td>
<td>1 gram of saturated fat or less, with not more than 15 percent of the calories coming from saturated fat</td>
</tr>
<tr>
<td>Lean</td>
<td>Less than 10 grams of fat, 4.5 grams of saturated fat and 95 milligrams of cholesterol</td>
</tr>
<tr>
<td>Extra lean</td>
<td>Less than 5 grams of fat, 2 grams of saturated fat and 95 milligrams of cholesterol</td>
</tr>
<tr>
<td>Light (lite)</td>
<td>At least one-third fewer calories or no more than half the fat of the regular product, or no more than half the sodium of the regular product</td>
</tr>
</tbody>
</table>
Structure Function Claims

• These claims describe the effect of a nutrient or dietary ingredient on normal structures or functions in the body.

• Unlike health claims, structure/function claims cannot explicitly or implicitly state a relationship between preventing, curing, or mitigating a disease or health-related condition and are not subject to FDA authorization or pre-market review.

• However, the manufacturer is responsible for ensuring that any structure/function claim on labels, like all information on food labels, is based on competent and reliable scientific research and is truthful and not misleading.
Example: Structure Function Claim
Health Claims Gone Wrong

NDC retracts diet claims

In the spring of 2007, the NDC retracted its claims of weight loss attributed to dairy consumption. The ad campaign featured slogans like, “Milk your diet. Lose weight!” and suggested that three servings of dairy products could contribute to weight loss. Another campaign called “Body by Milk”, was aimed at teenagers. It featured Alex Rodriguez, third baseman for the New York Yankees, and Carrie Underwood, an “American Idol” winner. According to a May 3 letter from the Federal Trade Commission (FTC) to the Physicians Committee for Responsible Medicine, the NDC agreed to retract the ads and marketing materials:

“until further research provides stronger, more conclusive evidence of an association between dairy consumption and weight loss.” [2]
Dietary supplements
Dietary Supplement Health and Education Act of 1994

• Supplement manufacturers do not need to receive FDA approval before marketing dietary supplements.[8] Also, DSHEA does not set a limit on the amount of vitamins or minerals which can be put into a pill.

• Label must have:
  • A statement of identity that contains the words "dietary supplement."
  • Nutrition information in the form of a "Supplement Facts" panel.
  • The part of the plant used, if an herb or botanical
  • A complete list of ingredients by their common or usual names
  • The disclaimer "This statement has not been evaluated by the Food and Drug Administration"
Creatine Monohydrate- Creatine is a metabolite that the body produces naturally. It is made up of three amino acids (L-methionine, L-arginine and L-glycine). Creatine promotes the available muscle energy in the body. Creatine monohydrate is found to contain more creatine per weight of material than other sources and works to accelerate recovery time and fat loss. Once in the body this product will attract the water around the muscle cell causing it to grow and enlarge. In this phase of hydration muscles will appear fuller, promote increased strength and will enhance the physical performance of the everyday athlete.

http://www.musclegauge.com/sportsups.htm
Things to keep in mind

• Consult your healthcare provider before taking dietary supplements to treat a health condition.
• Get your healthcare provider’s approval before taking dietary supplements in place of, or in combination with, prescribed medicines.
• If you are scheduled to have any type of surgical procedure, talk with your healthcare provider about any supplements you take.
• Keep in mind the term “natural” doesn’t always mean safe. Some all-natural botanical products, for example, like comfrey and kava, can harm the liver. A dietary supplement’s safety depends on many things, such as its chemical makeup, how it works in the body, how it is prepared, and the amount you take.
• Before taking any dietary supplement, use the information sources listed in this brochure and talk to your healthcare providers to answer these questions:
  • What are its potential benefits for me?
  • Does it have any safety risks?
  • What is the proper dose to take?
  • How, when, and for how long should I take it?

https://ods.od.nih.gov/factsheets/WYNTK-Consumer/
Dietary Supplements Include:

- Vitamins and minerals
- Amino acids
- Enzymes
- Herbs
- Animal extracts
- Plant extracts
- Probiotics
- Prebiotics

They come in a number of forms, including capsules, liquids, and powders. But while dietary supplements might seem similar to drugs, and some even have drug-like effects, there's a big difference:

**Dietary supplements don't undergo FDA review for safety and effectiveness before they're sold.**

https://www.consumer.ftc.gov/articles/0261-dietary-supplements
Other things to keep in mind about dietary supplements

• Dietary supplements aren’t always safe or harmless
• Supplements claiming to be cures aren’t proven

• Tip-offs to fraud
  • Claims that one product does it all and cures a wide variety of health problems
  • Suggests the product can treat or cure diseases
  • Words like scientific breakthrough, miraculous cure, exclusive product, secret ingredient, ancient remedy
  • Misleading use of scientific-sounding terms
  • Phony references to Nobel Prize winning technology or science
  • Undocumented testimonials by patients or doctors claiming miraculous results
  • Limited availability and a need to pay in advance
  • Promises of no-risk, money-back guarantees

https://www.consumer.ftc.gov/articles/0261-dietary-supplements
https://www.ftc.gov/news-events/media-resources/truth-advertising/health-claims
Dietary Supplements Verification Program - USP

• USP Dietary Supplement Verification Program is a voluntary program open to manufacturers of dietary supplement finished products from around the world.

• Through a rigorous testing and auditing process, USP evaluates voluntarily submitted products against science-based quality standards – including federally recognized USP–NF standards of quality, purity, potency, performance, and consistency – and FDA current good manufacturing practices.

• https://www.usp.org/verification-services/dietary-supplements-verification-program
Summary

Nothing beats the nutrient power of a healthy diet.

Image: https://twistwest.org/lifestyle-categories/healthy-diet/balanced-diet
Next week – The power of protein!