

Statutory and Regulatory Framework for the Labeling of Food

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“Functional Foods” Public Hearing –
December 5, 2006



General Labeling Provisions

- FDA's authority to regulate food labeling is provided in three laws, as amended:
 - Federal Food, Drug, and Cosmetic Act (FFDCA)
 - Fair Packaging and Labeling Act (FPLA)
 - Public Health Service Act (PHSA)



Use of the term 'Functional Foods'

- Private sector
 - Foods developed and marketed as foods for health
 - Provide a health benefit beyond basic nutrient content (International Food Information Council)
- Federal Food, Drug, and Cosmetic Act and the Code of Federal Regulations
 - Term is not recognized or defined as a category of food
 - Regulated under the same framework as other conventional foods



Provisions Regarding False or Misleading Labeling

- Section 403(a)(1) and 201(n) of the FFDCFA (21 U.S.C. 343(a)(1) and 321 (n))
 - Food is misbranded if its labeling is false or misleading in any particular
 - In determining whether labeling is misleading, FDA and courts take into account
 - representations made or suggested “by statement, word, design, device or any combination thereof”
 - whether the labeling fails to reveal facts material in light of representations in the labeling or with respect to consequences which may result from the use of the article to which the labeling relates under conditions prescribed or suggested in the labeling or under customary conditions of use.



Background: Label Claims for Foods

- 1990 Nutrition Labeling and Education Act (NLEA) was enacted
 - Provided for health claims based on significant scientific agreement (SSA) in food labeling.
- 1994 Dietary Supplement Health and Education Act (DSHEA) was enacted
 - Provided for structure/function claims, claims of general well-being, and nutrient deficiency claims in dietary supplement labeling



Background: Label Claims for Foods

- 1999: Pearson vs. Shalala (US Court of Appeals for the D.C. Circuit)
 - 1st amendment protection of commercial speech
 - FDA must permit claims that do not meet SSA, if properly qualified to prevent consumers from being misled.
- 2003 Task Force Report: *Consumer Health Information for Better Nutrition (CHIBN)*
 - Interim guidance for review of qualified health claims for both conventional foods and dietary supplements

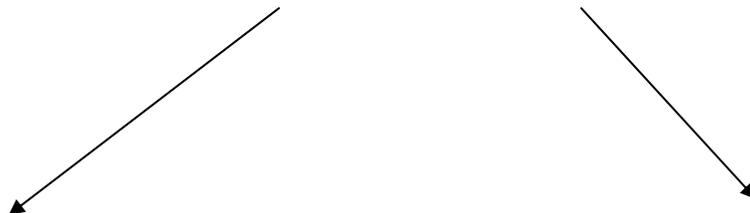


Goals of NLEA, 1990

- To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets,
- To eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent,
- To help consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims, and
- To encourage product innovation through the development and marketing of nutritionally improved foods.



Goals of NLEA



Nutrition Facts
 Serving Size 1 cup (228g)
 Servings Per Container 2

Amount Per Serving

Calories 250	Calories from Fat 110
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% Daily Value*

Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	

Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Authorization of Health claims
 and
 Nutrient Content claims



Types of Claims Related to Health and Nutrition in Labeling of Conventional Foods and/or Dietary Supplements

- Dietary Guidance
 - Message that refers to a general category of foods and health
 - Cannot convey an implied health claim
- Nutrition Support Statements
 - Structure/Function Claims
 - Well-being claims
 - Classical nutrient deficiencies (+prevalence)



Types of Claims Related to Health and Nutrition in Labeling of Conventional Foods and/or Dietary Supplements

- Nutrient Content Claims
 - Reference to the nutritional profile of a product
- Health Claims, including qualified health claims
 - Characterizes a relationship between a food or food component and a disease or health-related condition



Use of Structure/Function Claims on Dietary Supplements

- **Structure/Function Claims**

- Describes the role of a nutrient or dietary ingredient intended to affect a structure or function in humans, or characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function.

- No claims about treating, mitigating, curing, diagnosing, or preventing disease (except health claims for which product qualifies).
- Manufacturer is responsible for accuracy and truthfulness (including substantiation).
- Disclaimer is required.*
- Agency must be notified 30 days after a product bearing the structure function claim is first marketed.



Disclaimer Required on Dietary Supplements for Structure/Function Claims

- *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.*

21 CFR § 101.93(c)



Nutrient Content Claims

- Describe the level of a nutrient or dietary substance
 - *Free; high; low; contains*
 - *Good or excellent source*
- Compare the level of nutrient or dietary substance to another food
 - *More; reduced; light (lite)*
- Implied nutrient content claim
 - *Healthy; only; high potency*
- Percentage Claims for dietary supplements
 - Simple percent claims with amount
 - Comparative percent claims



Nutrient Content Claims

- Nutritional criteria for making Nutrient Content Claims are based on the Reference Daily Intakes (RDI) or the Daily Reference Values (DRV) established in 21 CFR §101.9(c).
 - Establish reference values
 - Example: “Excellent source of vitamin C” means that the product contains at least 20% of the RDI for vitamin C per reference amount customarily consumed.



Purpose of Health Claims

- To allow foods (including dietary supplements) to bear certain science-backed claims about reducing disease risk in their labeling without being regulated as drugs
- Risk reduction claims
 - Health claims are about **reducing the risk of a disease** or health-related condition, not treating, mitigating, or curing diseases.

Whitaker v. Thompson, 353 F.3d 947 (D.C. Cir. 2004)



Elements of a Health Claim

- “Substance”
 - A specific food or component of food, whether in conventional food or dietary supplement form.
 - Is related to nutritive value
See 21 C.F.R. 101.14(a)(2)(3).
- “Disease or health-related condition”
 - “Damage to an organ, part, structure, or system of the body such that it does not function properly ... or a state of health leading to such dysfunctioning ... ” 21 CFR 101.14(a)(5).
 - Nutrient deficiency diseases (e.g., scurvy) are not included in this definition.

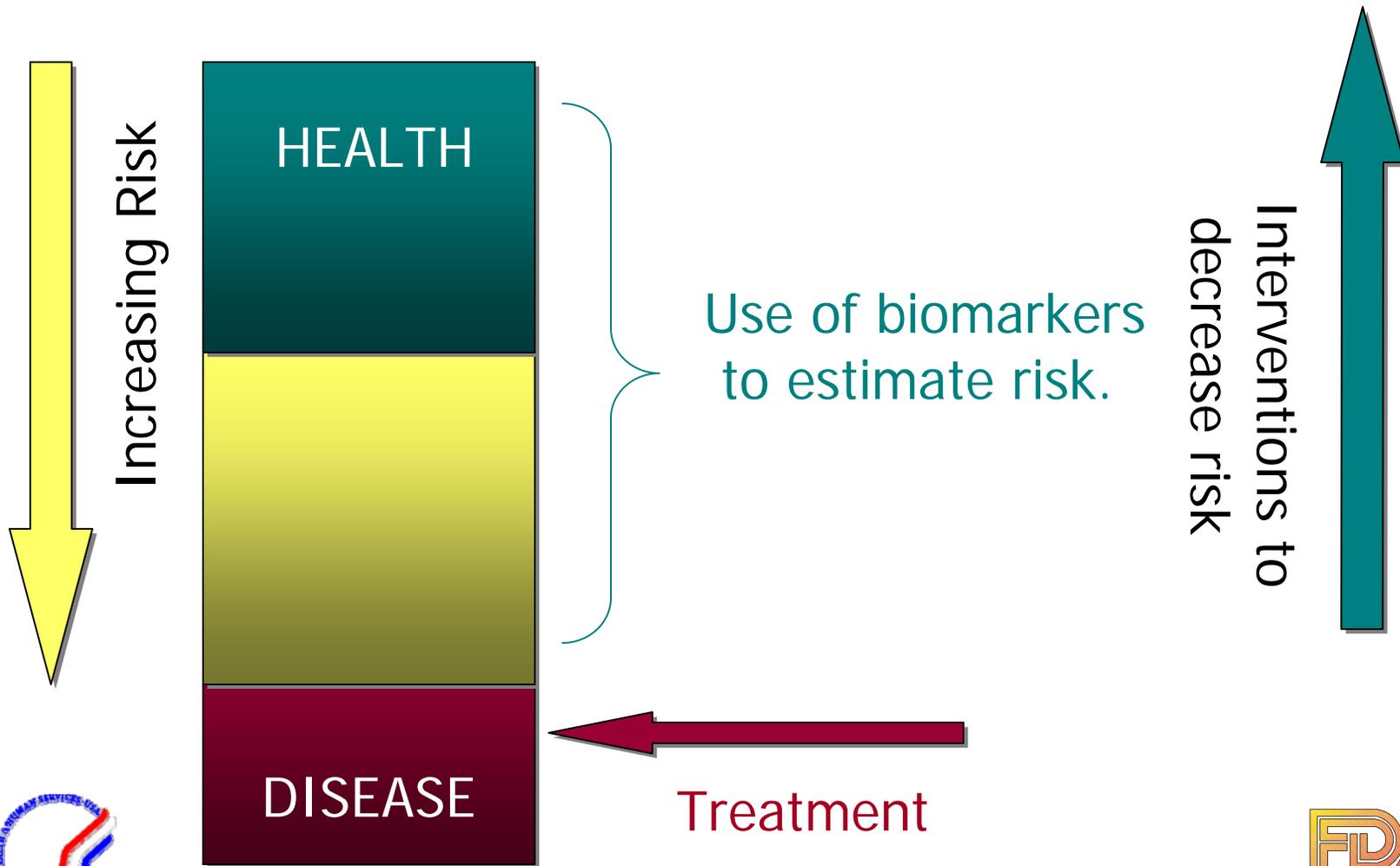


Nutritive Value

- A value in sustaining human existence by such processes as promoting growth, replacing lost nutrients, or providing energy (21 CFR 101.14(a)(3))
- Substances that have been considered in health claims, including qualified health claims (calcium, soluble fiber, DHA and EPA, lycopene, sodium, green tea, folic acid etc.)



Reducing Risk for Disease



Health Claims in Food Labeling

- NLEA Health Claims
 - Based on significant scientific agreement
 - Authorized through rulemaking
- Qualified Health Claims
 - Claims that characterize the quality and strength of the scientific evidence if the claim is **not** based on significant scientific agreement.
 - Use of enforcement discretion by the agency



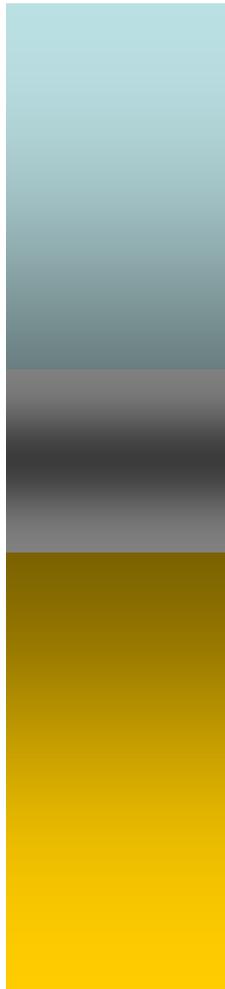
Health Claims in Food Labeling

- Claims based on authoritative statements
 - Based on authoritative statements of a scientific body of the government or of the National Academy of Sciences
 - Notification process



Continuum of Scientific Evidence

Strength and consistency of scientific evidence



Scientific Consensus

Significant Scientific Agreement: Body of consistent, relevant evidence from well-designed clinical and/or epidemiological studies.

Emerging Evidence

- not conclusive
- limited and not conclusive
- very limited and preliminary evidence; little scientific evidence to support
- benefit is highly unlikely/uncertain



FDA Policy on Nutrient Fortification of Foods

- Recognizes the public health importance of achieving and maintaining a desirable level of nutritional quality in the food supply
- Is intended to prevent over or under fortification, nutrient imbalances, and deceptive or misleading claims for certain foods
- Does not encourage indiscriminate addition of nutrients
- Identifies foods that are not appropriate for fortification (fresh produce; meat, poultry or fish products; sugars; snack foods such as candies or carbonated beverages).



21 CFR § 104.20



Examples of Where Fortification Might be Appropriate

- Correction of a dietary insufficiency
- Restoration of nutrients lost in processing and handling of foods
- Balancing the vitamin, mineral, and protein content of a food in proportion to the caloric content of the food
- Use in replacements for traditional foods to avoid nutritional inferiority
- Compliance with other regulations (e.g., standards for enriched products)



21 CFR § 104.20



Principles for Nutrient Addition to Foods

- Stable under customary conditions of storage, distribution and use
- Physiologically available from the food
- The level will not result in excessive intake of the nutrient considering other sources of the nutrient
- Is suitable for its intended purpose and in compliance with other regulations on safety of substances in foods.



21 CFR § 104.20



2005 *Dietary Guidelines for Americans*

- Based on the latest scientific evidence... the DGA is the primary source of dietary health information for policymakers, nutrition educators, and health providers.
- “A basic premise of the *Dietary Guidelines* is that nutrient needs should be met primarily through consuming foods.”
- “In certain cases, fortified foods and dietary supplements may be useful sources of one or more nutrients that otherwise might be consumed in less than recommended amounts. However, dietary supplements, while recommended in some cases, cannot replace a healthful diet.”



