



Regulatory Framework for Food Labeling related to Nutrition

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CFSAN-FDA

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)

Mandatory Label Requirements for foods, including dietary supplements

- The label must contain:
 - Identity of food
 - Ingredient statement
 - Amount of food in package
 - Name and place of business
 - ➔ Nutrition information (unless exempt)
 - Information disclosing material facts about the food
 - Allergen labeling

Nutrition Labeling

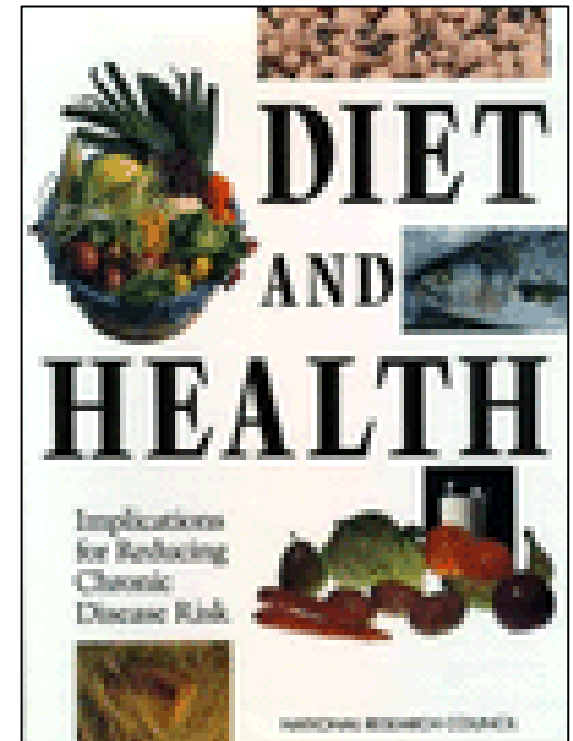
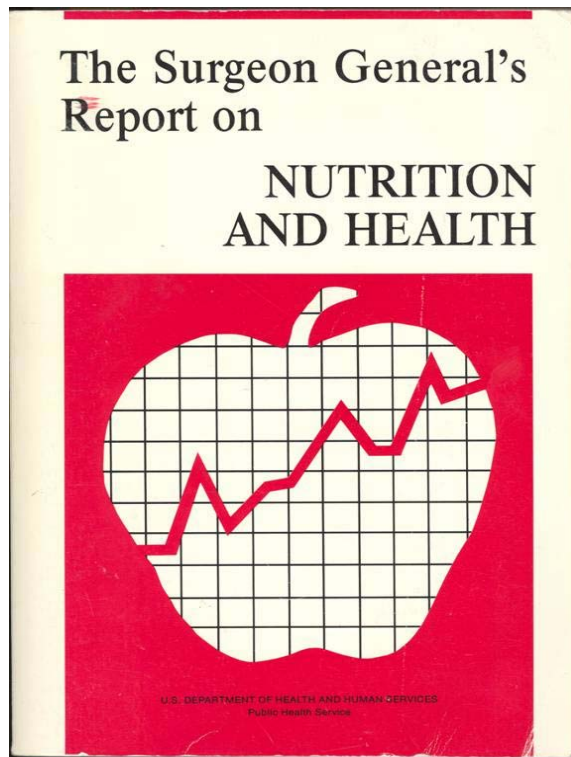
- Nutrition Labeling and Education Act (NLEA) - 1990
 - Made nutrition information mandatory on most packaged foods
 - Specified format and content for nutrition labeling
 - Provision for nutrient content claims and health claims on foods



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.

Scientific Basis for Implementation of NLEA



Goals of Nutrition Labeling and Education Act of 1990

Nutrition Facts

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

Amount Per Serving

Calories 250 Calories from Fat 110

% 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:

		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 Food Labeling

- 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 Food Labeling

- Nutrient Content Claims
 - A claim on the label or in labeling of foods that expressly or implicitly characterizes the level of a nutrient in the food.
- Health Claims, including qualified health claims
 - Characterizes a relationship between a food or food component and a disease or health-related condition



Nutrient Content Claims

- Relevant Regulations
 - 21 CFR 101.13 Nutrient Content Claims-General Principles
 - Subpart D of Part 101-Specific requirements for Nutrient Content Claims
- Specific Regulatory Information
 - Established Daily Value
 - Definition of terminology
 - Style and size of font
 - Disclosure statement based on levels of fat, saturated fat, cholesterol or sodium

Expressed 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)*
- Percentage Claims for dietary supplements
 - Simple percent claims with amount
 - Comparative percent claims



Examples of Expressed Claims

- ‘Good’ source
 - At least 10% of RDI or DRV (i.e. DV)
- High or excellent source
 - At least 20% of the RDI or DRV (i.e. DV)
- Free or low
 - Grams or mg per RACC or labeled serving are defined based on nutrient
- Reduced
 - At least 25% less per RACC than an appropriate reference food

For all nutrient content claims, regulations contain additional conditions and criteria for use and other synonyms for the terms.

Implied Nutrient Content Claims

- Suggests that a nutrient is present or absent in a certain amount
 - e.g. *“contains no oil”*; *“only”*
- Equivalence claims
 - e.g. *“as much vitamin C as an 8 oz of orange juice”*
- Claims that a food may be useful in maintaining healthful dietary practices
 - e.g. *Healthy*



Criteria for use of “healthy”

	Individual Food* (RACC is \geq 30 g)	Seafood/Game Meat	Main Dish/Meal Product
Total Fat	3 g or less /RACC (low)	Less than 5 g per RACC & 100g	3 g or less/100g & no more than 30% of calories (low)
Saturated Fat	1 g or less/RACC & 15% or less calories (low)	Less than 2 g per RACC and 100g	1 g or less/100 g & <10% of calories (low)
Sodium	480 mg or less/RACC & /labeled serving	480 mg or less/RACC & /labeled serving*	600 mg or less per labeled serving
Cholesterol	60 mg or less/RACC & /labeled serving	Less than 95 mg/RACC & 100g	90 mg or less per labeled serving
Beneficial Nutrients	At least 10% RDI or DRV per RACC for one or more of vitamins A, C, iron, calcium, protein, or fiber [‡]		Main dish: 2 nutrients; Meal: 3 nutrients

*For foods with a RACC of 30 g or less or 2 tablespoons or less, the criteria refer to the amount per 50 g of food.

[‡]Except raw fruits and vegetables; frozen or canned single ingredient/mixture fruits and vegs, except that ingredients whose addition does not change the nutrient profile of the fruit or veg may be added; enriched cereal-grain products that conform to a standard of identity.

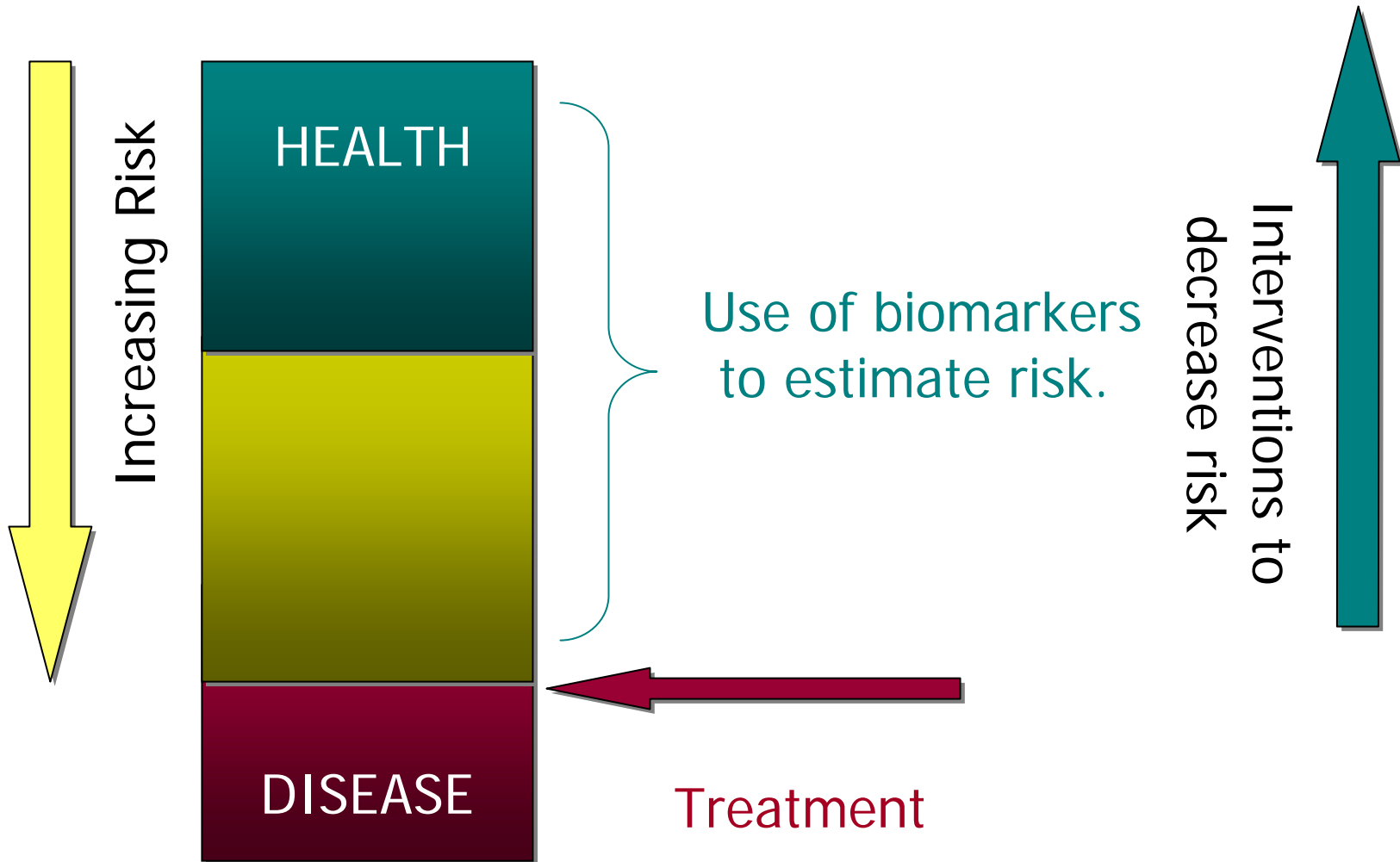
RACC = Reference amount customarily consumed, which is the basis of serving size on food labels.

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)

Reducing Risk for Disease





Elements of a Health Claim

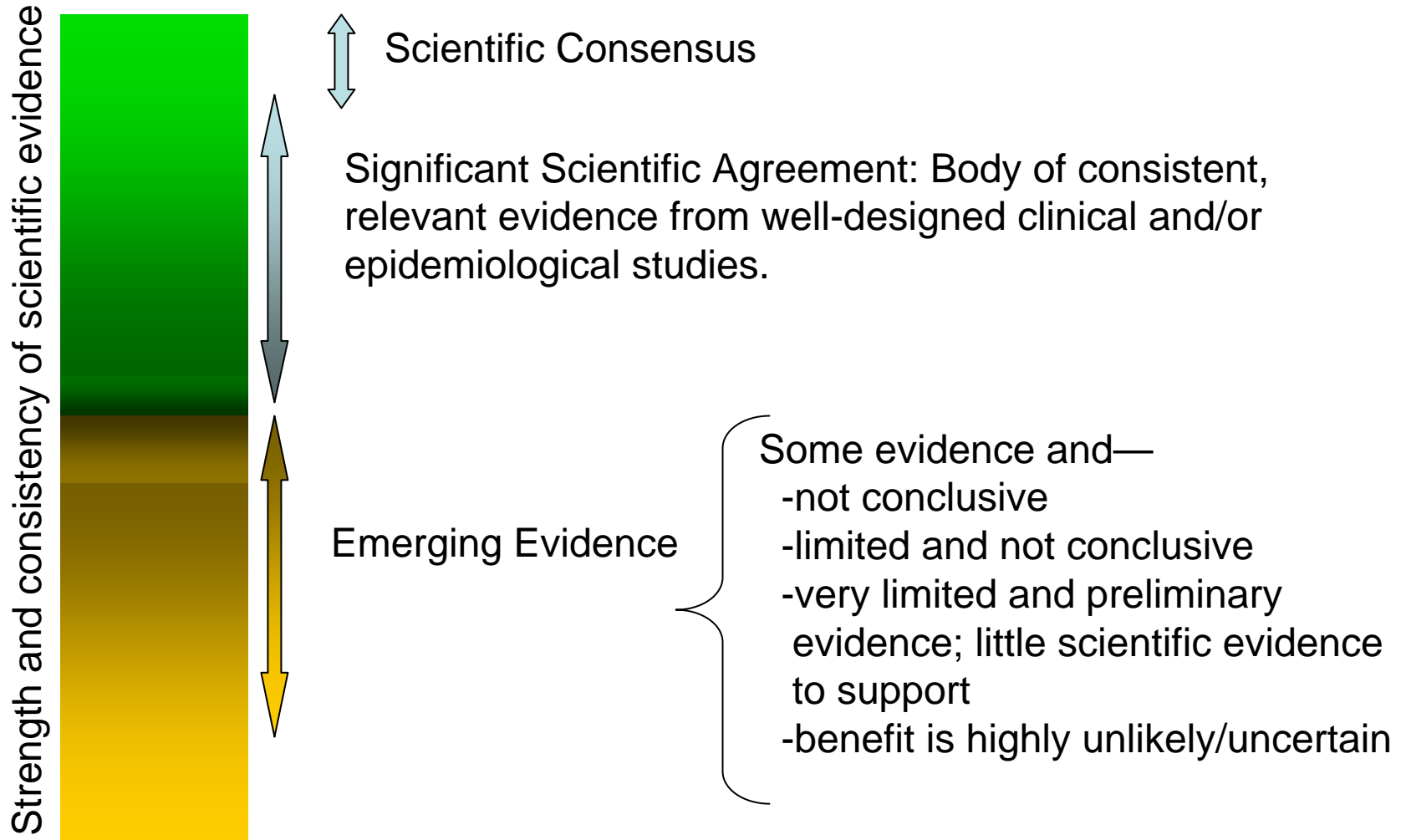
- “Substance”
 - A specific food or component of food, whether in conventional food or dietary supplement form.
 - Is related to nutritive value
See 21 C.F.R. 101.14(a)(2)(3).
- “Disease or health-related condition”
 - “Damage to an organ, part, structure, or system of the body such that it does not 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.



Health Claims used in food labeling that require pre-market review

- Claims authorized by FDA
 - Based on significant scientific agreement
 - Authorized through rule-making
- Qualified Health Claims
 - Claims that characterize the quality and strength of the scientific evidence if the claim is not based on significant scientific agreement.
 - Agency exercises enforcement discretion under interim guidelines

Continuum of Scientific Evidence





Steps in health claim process

- A petition is submitted to the agency
Reviewed for completeness and consistency with requirements of health claims
- The scientific evidence is evaluated.
Rulemaking initiated for claims based on SSA
Enforcement discretion for qualified health claims
- Conditions for use of the claim are determined.

See: <http://www.cfsan.fda.gov/label.html>

Reviewing the Evidence

- Define substance/disease relationship
- Identify relevant studies
- Classify studies
- Rate studies for quality
- Rate for strength of body of evidence:
Quantity, quality, consistency, relevance
- Report “rank”

Scientific Evaluation.

- Assessment of the scientific evidence
 - Identification of relevant scientific information
 - Research synthesis (Meta-analyses and review articles)
 - Animal and *in vitro* data
 - Intervention studies in humans
 - Observations studies in humans

Scientific Evaluation

- Assessment of the scientific evidence
 - Research synthesis (Meta-analyses and review articles)
 - Used to identify additional reports that might be useful
 - Do not provide sufficient information on study detail needed for the evaluation
 - Animal and *in vitro* data
 - Background information; hypothesis generating; explore mechanism of action

Scientific Evaluation

- Assessment of scientific evidence cont.
 - Human studies
 - Methodological evaluation considers
 - Placebo controls
 - Management of bias and confounders
 - Data collection (e.g. dietary assessment)
 - Quality of statistical analysis
 - Outcome measured (e.g. disease incidence or surrogate endpoint)

Diseases and Validated Modifiable Risk Factors

- **Coronary Heart Disease**
Total/LDL cholesterol, blood pressure
- **Colorectal Cancer**
Polyps
- **Diabetes**
Blood sugar levels, insulin resistance
- **Osteoporosis**
Bone mineral density
- **Dementia**
Mild cognitive impairment

Scientific Evaluation

- Rate the strength of the useful, publicly available evidence
 - Study type
 - Intervention
 - Observational studies: prospective cohort, case-control, cross-sectional
 - Methodological quality
 - Quantity of evidence
 - Support for relationship in the U.S population or a subgroup
 - Replication and consistency of the findings
- What is the level of comfort among qualified experts that the health claim relationship is scientifically valid?

Study Design Elements that Can Prevent Making a Scientific Conclusion for a Health Claim

- No control group
- No statistics conducted between control and intervention group
- Presence of key confounders of risk (e.g., smoking and lung cancer)
- Observational study does not describe the process for validating the dietary assessment method
- Studies conducted on a malnourished population
- Studies conducted in individuals with the disease



U.S. Food and Drug Administration



Department of
Health and
Human Services

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Nutrition, Labeling and Dietary Supplements
July 2007: Docket No. 2007D-0125

Guidance for Industry

Evidence-Based Review System for the Scientific Evaluation of Health Claims

Draft Guidance

Important elements in identifying credible scientific evidence

- What is the substance and disease?
- What scientific evidence is relevant?
- Is the evidence suitable for an evidence-based review?
- Can scientific conclusions be drawn from the evidence?



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



Implied Health Claims

- Statements, symbols, vignettes or other forms of communication that suggest a relationship between the presence or level of a substance in the food and a disease or health-related condition.
 - Examples: third party references, terms or symbols such as “heart”

Use of disclosure and disqualifying statements with claims

- **Disclosure:** Requirement for disclosure levels with *nutrient content claims*.
 - If a product exceeds certain levels for fat, saturated fat, cholesterol, or sodium
 - “See nutrition information for _____ content.”
- **Disqualifying Criteria:** For use of *health claims*, a product must meet certain criteria, including:
 - Food contains, without fortification, 10% or more of the DV for one or more of vitamin A, vitamin C, iron, calcium, OR fiber
 - Food contains less than a specified level for total fat, saturated fat, cholesterol, or sodium.

Conditions on the Use of a Health Claim

- Disqualifying levels for
 - Total fat
 - Saturated fat
 - Cholesterol
 - Sodium
 - Nutrient level
- Rationale for exemptions is based on scientific evidence.

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Label Information

- **Mandatory**
 - Required by relevant statutes and governed by regulations in the Code of Federal Regulations
 - must appear on **Principal Display Panel (PDP)** or in the **Information Panel**
- **Voluntary**
 - Used at Manufacturer's discretion (Claims, marketing statements, promotions, etc.)
- All labeling must be truthful and not misleading



Provisions Regarding False or Misleading Labeling

- Section 403(a)(1) and 201(n) of the FFDCA (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.



Current Activities

- **Recent Public hearings**

- Docket No. 2007N-0277 Food labeling: Use of Symbols to communicate Nutrition Information, Consideration of consumer Studies and Nutritional Criteria.
- Docket No. 2002P-0122: Conventional Foods Being Marketed as “Functional Foods”

- **Advanced Notice of Proposed Rulemaking**

- Docket No. 2006N-0168 Food Labeling: Revision of Reference Values and Mandatory Nutrients

Current Activities

- **Re-evaluation of health claims**

- 21 CFR 10.25(b): The Commissioner may initiate a proceeding to issue, amend, or revoke a regulation or take or refrain from taking any other form of administrative action.
- FDA may, on its own initiative, decide to reconsider a determination (Consumer Health Information for Better Nutrition Initiative Task Force Final Report, 2003).

- **Claims to be re-evaluated (Docket No. 2007N-0464)**

- Soy Protein and CHD (21 CFR 101.82)
- Dietary lipids (fat) and cancer (21 CFR 101.73)
- Antioxidant vitamins (E and C) and risk of certain cancers (QHC)
- Selenium and certain cancers; and anticarcinogenic effects (QHC)



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