Nutritional Criteria for Labeling Claims

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Presentation Outline

- Regulatory Framework for Nutrition Labeling
- Current activities and priorities
- Challenges for consideration by the Committee
Approaches FDA has used to define nutrient criteria for claims

- Nutrient content claims
- Implied nutrient content claims
- Nutrient levels for disclosure statement with nutrient content claims
- Nutrient levels to disqualify products from bearing health claims
- Questions raised by FDA in a 2003 ANPRM* about dietary guidance statements

*Advanced Notice of Proposed Rulemaking
Legal Authority for Food Labeling

- Federal Food, Drug and Cosmetic Act (FFDCA)
- Fair Packaging and Labeling Act
- Public Health Service Act
Purpose of Labeling

- Informs consumer at point of purchase about, among other things:
  - The basic nature of the food
  - Ingredients used to make the food
  - Nutritional attributes about the food
  - Other material/essential information about the food (i.e., warnings/clarifications)
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 - 1990
  – Amended the FFDCA and made nutrition information mandatory on most packaged foods
  – Specified format and content for nutrition labeling
    • Nutrition Facts
      – Shifted emphasis toward macronutrients associated with chronic disease risk
      – Allowed 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.
- Federal pre-emption
Claims Related to Health and Nutrition on Foods and/or Dietary Supplements that do not require pre-approval

- **Dietary Guidance**
  - Message that refers to a general category of foods and health

- **Nutrition Support Statements**
  - Statements of well-being
  - Structure Function Claims
  - Classical nutrient deficiencies (+prevalence)
Claims Related to Health and Nutrition on Foods and/or Dietary Supplements that require pre-approval

• Nutrient Content Claims
  – Reference to the nutrient level in a product

• Health Claims
  – Characterizes a relationship between a food or food component and reducing risk of disease or health-related condition
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

<table>
<thead>
<tr>
<th>Type of claim</th>
<th>Criteria</th>
<th>Synonyms</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Good” source</td>
<td>At least 10% of RDI or DRV (i.e. DV)</td>
<td>provides, contains etc.</td>
<td>Cannot use without an established DV.</td>
</tr>
<tr>
<td>“High” source</td>
<td>At least 20% of the RDI or DRV (i.e. DV)</td>
<td>excellent, etc.</td>
<td></td>
</tr>
<tr>
<td>Free or low</td>
<td>Grams or mg per RACC or labeled serving based on nutrient</td>
<td>Zero, without, insignificant; little, small amount etc.</td>
<td>See regulations for additional terms and criteria.</td>
</tr>
<tr>
<td>Reduced</td>
<td>At least 25% less per RACC than an appropriate reference food</td>
<td>Less, fewer etc.</td>
<td></td>
</tr>
</tbody>
</table>

Terms: RDI=Reference Daily Intake, DRV=Daily Reference Value; DV=Daily Value; RACC=Reference Amount Customarily Consumed
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”

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

*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 veggies, 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.
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.
- Elements of a Health Claim
  - Substance: A specific food or component of food, whether in conventional food or dietary supplement form. 21 C.F.R. 101.14(a)(2).
  - Disease or health-related condition as described in 21 CFR 101.14(a)(5).
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.
Minimum levels for disclosure or disqualifying requirements on claims

<table>
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<th>Main Dish product</th>
<th>Meal Product</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>per RACC</td>
<td>per labeled serving</td>
<td></td>
</tr>
<tr>
<td>Fat, g</td>
<td>13.0</td>
<td>19.5</td>
<td>26.0</td>
</tr>
<tr>
<td>Saturated fat, g</td>
<td>4.0</td>
<td>6.0</td>
<td>8.0</td>
</tr>
<tr>
<td>Cholesterol, mg</td>
<td>60</td>
<td>90</td>
<td>120</td>
</tr>
<tr>
<td>Sodium, mg</td>
<td>480</td>
<td>720</td>
<td>960</td>
</tr>
</tbody>
</table>

*If RACC is 30 g or less, the criteria are based on amount per 50g. RACC=Reference amount customarily consumed.
Questions raised in the 2003 ANPRM*

• Definition of dietary guidance statements; approaches to distinguish from nutrient content and health claims
• Dietary guidance statements on substitution or replacement of foods
• Development of dietary guidance statements by Federal agencies
• Criteria for assessing the scientific validity of these statements.
• Criteria needed to so that statements are truthful and not misleading

*Part of activity from Task Force on Consumer Information for Better Nutrition Initiative.
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Factors considered by FDA in developing nutrient criteria for claims

- Public health significance
- Reference values for intake
- Distribution among food groups
- How do reference values for daily intake apply to individual foods, meals, or main dishes?
Questions related to nutritional criteria

- How can the nutritional criteria developed by FDA be used in front-of-pack labeling systems?
  - Which criteria are applicable?
  - Does the current approach apply to front-of-pack systems?

- Are there additional nutrients or factors that should be considered?
  - What is the evidence base for these factors?
  - Some examples: added sugars, nutrients to encourage, food categories to encourage.
FDA Activities Related to Front-of-Pack Labeling

- Docket No. 2007N-0277 Food labeling: Use of Symbols to communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria.
- Guidance on front-of-pack symbols or logos that can be considered nutrient content claims (Dear Manufacturer letter) December 2008
- Letter to Industry regarding point-of-purchase food labeling. October 2009
- Consumer studies regarding the use and understanding of front-of-pack claims