



Food Labeling: Nutrient Content, Health, and Other Claims

Introduction to Food Law & Regulation Course: March 28-29, 2022

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Agenda

- Reminders
- Nutrient Content Claims
- Health Benefit Claims
 - Health Claims & Structure-Function Claims
- Other Marketing Claims
 - Natural, Organic, Gluten-free

How Does FDA Regulate Claims?

- FDC Act 403 (a)(1) – “A food shall be deemed to be misbranded– [] If [] its labeling is false or misleading in any particular . . .” or fails to conform with requirements specified in section 403.
- FDC Act 201(n) – Labeling claims that fail to disclose “material facts” cause a food to be misbranded.
- FDC Act 403(r): Use of unapproved nutrient content or health claims in labeling causes food to be “misbranded.”

Federal Preemption

- The NLEA prohibits states from imposing requirements relating to food labeling that are not identical to an applicable federal food labeling standard.
- State and consumer actions under state law incorporating FDC Act.
- Compliance is important.



NUTRIENT CONTENT CLAIMS, OTHER “NUTRITIONAL ATTRIBUTE” CLAIMS

What claims concerning amounts of nutrients in a food are permitted?

- “Nutrient content claims”:
 - FDC Act 403(r) – A food is misbranded if labeling includes a claim that is not approved/authorized by FDA “which **expressly or by implication characterizes the level of any nutrient** which is of the type required [in nutrition labeling].”
- Notified nutrient content claims

Express Nutrient Content Claims

Direct statements about the level (amount) or range of a nutrient in food

- Absolute Claims (e.g., low fat, cholesterol free, good source of vitamin D, high in antioxidant vitamin E)
- Relative Claims (e.g., lower fat, enriched, more...)

Implied Nutrient Content Claims

“Implicitly characterize” a nutrient level and are permitted if the food qualifies for the nutrient content claim implied.

- Describe the food or an ingredient in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., high in oat bran); or
- Suggest that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., healthy). 21 C.F.R. § 101.13

Nutrient Content Claims

May not be made unless:

- Authorized by FDA
 - 21 C.F.R. Part 101, Subpart D (authorized nutrient content claims)
- Notified: Through petition or FDAMA notification (claims based on authoritative statement of U.S. government or NAS).

POLL:

Which claims are not nutrient content claims?

1. “gluten-free”
2. “Packed with antioxidants”
3. “no preservatives”;
4. “Good Source of Calcium”
5. “100% whole grain oatmeal”;
6. “corn oil”

NOT Nutrient Content Claims

- Non-nutritional Ingredient Claims: Claims that convey no express or implied claim characterizing the level of a nutrient in the food.
 - Avoidance Claims (e.g., “gluten-free”);
 - Nonnutritive Claims (e.g., “no preservatives”);
 - Added Value Claims (e.g., “100% whole grain oatmeal”);
 - Statements of Special Dietary Usefulness (e.g., weight control); and
 - Non-quantitative Statements of Identity (e.g., “oat bran muffins” or “corn oil”)

See 21 C.F.R. § 101.13, 101.65.

Nutrient Content Claims

- General Principals for Claims, 21 C.F.R. § 101.13
 - Consistent with dietary guidelines
 - Consistent across terms and nutrients
 - Based on RACC [primarily]
 - Only for nutrients with Daily Values
 - **Only claims defined by regulation**

Express Nutrient Content Claims

- Good source/Contains/Provides/With
 - 10-19% of the DRV or RDI per RACC
- High/Rich in/Excellent Source of:
 - 20% or more of the DRV or RDI per RACC

Beware of use of terms such as “packed with,” “loaded,” “source of” ... terms not defined by FDA.

Express Nutrient Content Claims

FREE

< 5 Calories	21 C.F.R. § 101.60(b)(1)
< 5 mg Sodium	21 C.F.R. § 101.61(b)(1)
< 0.5 g Total Fat	21 C.F.R. § 101.62(b)(1)
< 0.5 g Saturated fat	21 C.F.R. § 101.62(c)(1)
< 2 mg Cholesterol	21 C.F.R. § 101.62(d)(1)
< 0.5 g Sugars	21 C.F.R. § 101.60(c)(1)

All per RACC and per labeled serving

- No trans fat free claim permitted
- No carbohydrate free claim permitted

! FDA suggests that 0g claims are not subject to regulation for no (or zero) claims!

Express Nutrient Content Claims

LOW

- Based on “per RACC” and, if the RACC is small, then per 50g (except for saturated fat)
- Unlike *Free* claim – not on per labeled serving
- Must be specifically processed or altered to be “low”
- Not defined for sugars, carbohydrates, or trans fat

Express Nutrient Content Claims

- “Good Source,” “high,” “more,” high potency,” and antioxidant claims. 21 C.F.R. § 101.54.
- “Light” or “lite.” 21 C.F.R. § 101.56.
- Sodium content claims. 21 C.F.R. § 101.61.
- Fat, fatty acid, and cholesterol content of foods. 21 C.F.R. § 101.62.
- Use of nutrient content claims for butter. 21 C.F.R. § 101.67.

Express Nutrient Content Claims; Relative Claims

- Relative Claims: Statements that compare the level of a nutrient in a food with the level of a nutrient in a reference food.
 - More/fortified/Enriched/Added/Extra/Plus:
 - Must have 10% or more of the DV per RACC and disclose reference food, detailed requirements.
 - Reduced/Less/Lower/Fewer:
 - 25% less per RACC
 - Defined for calories, fat, sat. fat, sodium, cholesterol, and sugars

“Relative” Nutrient Content Claims

- Reference Food: May compare against regular brand, competitor’s brand, or a representative nutrient value for a market-basket category of food (required for light claims).
- Disclosure Statements:
 - PDP “Reduced fat – 50 % less fat than regular ice cream”
 - PDP/IP “4 grams of fat compared with 8 grams fat per serving of regular ice cream”

Healthy as Implied Nutrient Content Claim

- 21 C.F.R. § 101.65(d) governs the use of the term “healthy” or similar terms such as “healthful.” Applies to:
 - The use of the term characterizes the level of a nutrient in food; or
 - Implies a judgment of the food itself.

Healthy as Nutrient Content Claim

- FDA Regulation: For a food to bear an implied “healthy” nutrient claims it must generally:
 - Not exceed certain FDA established levels for fat, saturated fat, sodium, and cholesterol;
 - Provide at least 10% of the reference daily value for vitamin A, vitamin C, calcium, iron, protein, or fiber; and
 - Comply with FDA’s fortification policy.
- But FDA guidance broadened use of healthy claim.
- FDA is considering rule making.
- BUT many consumer class actions have asserted that presence of sugar in a food (e.g., cereal) disqualifies food from being healthy even though the regulation does not specify that as a requirement! 🤔

Quantity & Percentage Claims

- Amount or percentage claims are permitted if they do not “characterize” the level of a nutrient in food (factual statements).

“100 Calories Per Serving”

NOT:

**“Only 100 Calories
Per Serving”**

Section 101.13(i)

- Unless expressly prohibited by regulation, statements describing the percentage contribution of vitamins and minerals in a conventional food or dietary supplement in relation to the RDI are permitted.
- E.g., 25% of the RDI for vitamin C.

“Disclosure levels”

- If a food for which a nutrient content claim is made contains fat (13 g), saturated fat (4g), cholesterol (60mg), or sodium (480mg) in excess of specified “disclosure levels” per RACC and per labeled serving (or for foods with small RACCS, per 50g) labeling must highlight the nutrient(s) that exceed(s) the level(s). 21 C.F.R. § 101.13(h).
- Mandatory disclosure statement must accompany nutrient content claim when disclosure levels are exceeded.

“See nutrition information for (e.g., fat content)”

Nutrient Content Claims & Standardized Food

- Compliance with the formulation and labeling requirements of 21 C.F.R. § 130.10 permits a standard of identity food to be nutritionally modified and maintain standardized status for legal purposes.
 - High Calcium Cottage Cheese
 - Low Fat Milk

Special Case: Nutrient Claims Foods for Infants & Children

- Infant formula:
 - See 21 C.F.R. Part 107.
- Percentage Daily Value claims for vitamins and minerals:
 - “100% vitamin C per serving”
- Taste claims:
 - Unsweetened
 - Unsalted

Carbohydrate, Whole Grain, Keto Friendly Claims

- FDA has not defined nutrient content claims for carbohydrates, whole grains, or keto (paleo etc.) friendly.
 - May make factual statements such as x g of carbohydrates per serving under 21 C.F.R. § 101.13(i)(3).

Requirements for Whole Grain Claims

*Contains Nonbinding Recommendations
Draft – Not for Implementation*

Guidance for Industry and FDA Staff

Whole Grain Label Statements

*Additional copies are available from:
Food Labeling and Standards Staff (HFS-820)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 301-436-2371
<http://www.fda.gov/ohrms/dockets/default.htm>*

U.S. Department of Health and Human Services
Food and Drug Administration

[February 2006]

Answer: Manufacturers can make factual statements about whole grains on the label of their products, such as “10 grams of whole grains,” “½ ounce of whole grains,” (21 CFR 101.13(i)(3)) and “100% whole grain oatmeal” (as percentage labeling under 21 CFR 102.5(b)), provided that the statements are not false or misleading under section 403(a) of the Act and do not imply a particular level of the ingredient, i.e., “high” or “excellent source.”

In addition, labels may bear a health claim based on an authoritative statement of a scientific body relating whole grains with a reduced risk of heart disease and certain cancers if the food meets the qualifications of one of the notifications submitted under section 403(r)(3)(C) of the Act (see <http://www.cfsan.fda.gov/~dms/labfdama.html>).



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Notified Nutrient Content Claims

- See FDA website: <https://www.fda.gov/food/food-labeling-nutrition/fda-modernization-act-fdama-claims> (NCC claims for choline and linoleic acid)

POLL:

Which claims are nutrient content claims?

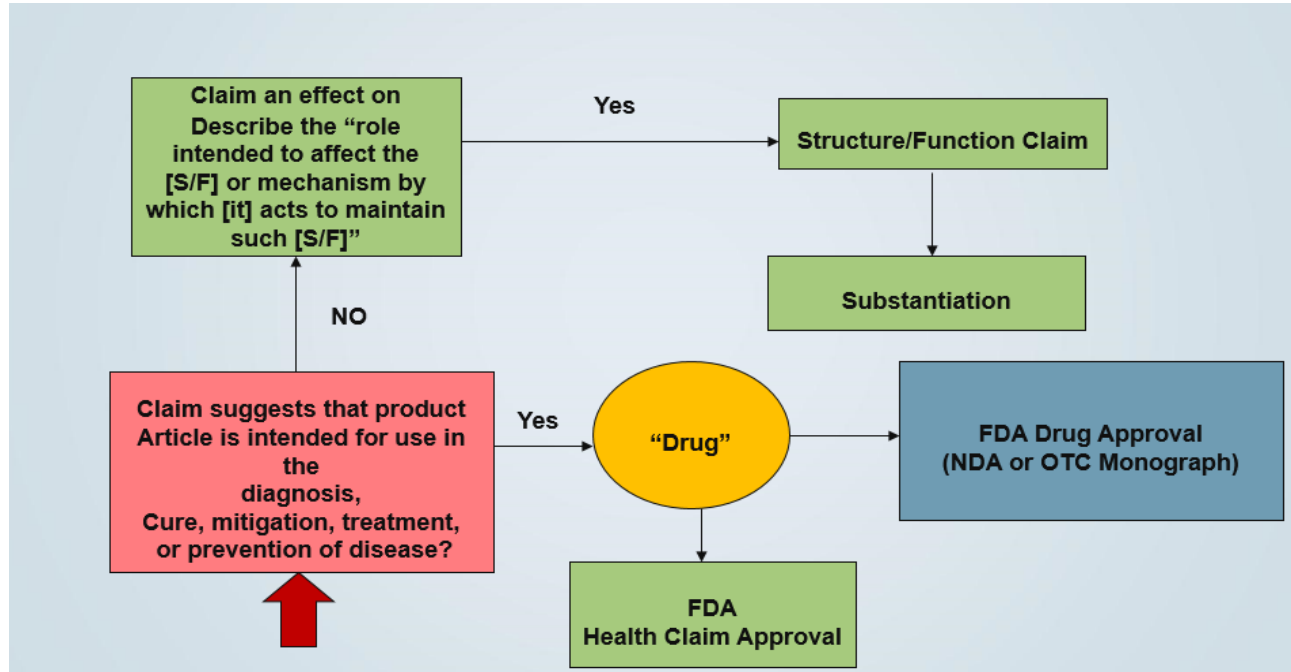
1. High in monounsaturated fat.
2. No artificial colors.
3. As much calcium as one 8 ounce glass of milk.
4. Bursting with vitamin E.
5. 300 g omega-3 fatty acids per serving.
6. Eat fruits and vegetables.

STRUCTURE-FUNCTION CLAIMS & HEALTH CLAIMS

Health Benefit Claims

- Structure Function Claims:
 - “Calcium helps build strong bones and teeth.”
- Health Claims:
 - “Calcium and vitamin D helps reduce the risk of osteoporosis.”
- General Dietary Guidance Claims:
 - Consuming 3 dairy servings per day helps ensure that your diet provides enough calcium and vitamin D to meet your needs.

Framework for Health Benefit Claims



What are “structure-function claims?”

- Structure function claims are claims that tout a food’s effect on the structure or function of the body.
- For (conventional) food, they are “permitted” under FDC Act 201(g)(1)(C) carve-out.
 - Defines a Drug as “articles (**other than food**) intended to affect the structure or any function of the body of man or other animals.”
 - Example: Fiber helps maintain bowel regularity.

Structure/Function Claims for Dietary Supplements

- DSHEA amended the FDC Act to expressly authorize structure/function claims for dietary supplements. See FDC Act 403(r)(6).
- FDA developed regulations regarding structure/function claims. 21 C.F.R. § 101.93.

Structure/Function Claims vs. Drug Claims

- S/F claim may not imply or express usefulness in the diagnosis, cure, mitigation, treatment, or prevention of disease.
 - Disease: 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 dysfunction, except (for DSS) diseases resulting from essential nutrient deficiencies not included (provided certain disclosures included).

Health Claims

- FDA definition: Claims that expressly or impliedly characterizes the relationship between a “substance” and a disease or health-related condition.
 - Include disease prevention claims.
- Implied health claims may include:
 - Third party certification symbol (AHA Heart Check);
 - Brand names, e.g., Arthritis Formulation; and
 - Vignettes, e.g., heart shaped symbol.

Health Claims

- FDC Act 403(r) – Requires FDA approval of health claims:
 - A food is misbranded if labeling includes a claim that is not approved by FDA which “expressly or by implication characterizes the relationship of any nutrient” in food “to a disease or health related condition.”
- A health claim may not be made expressly or impliedly on the label or in labeling unless specifically authorized by FDA or notified health claim (FDAMA) or....

Limitations on Health Claims

- **The “Jelly Bean Rule”** --Food products bearing a health claim (with notable exceptions for sugar alcohol/dental caries health claims) must contain, before any nutrient addition, 10% or more of the DV for vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC.
 - Exceptions granted on a case-by-case basis.
- **“Disqualifying Levels”** of “risk increasing” nutrients.
 - Same as “disclosure levels” for nutrient content claims.

FDA Authorized Health Claims

- **FDA issues regulation pursuant to Petition.**
- **“Significant Scientific Agreement Health Claims”** – FDC Act 403(r) requires FDA to issue a health claim regulation authorizing health claims supported by scientific evidence meeting the “significant scientific agreement” standard. (SSA Health Claims).
 - Scientific evidence establishes validity of a diet/disease relationship.
 - Approved health claims are codified at 21 C.F.R. Part 101, subpart E.

SSA Health Claim Requirements & Model Claims

Requirements for Health Claims Made in Labeling			
Approved Claims	Requirements for the Food	Claim Requirements	Model Claim, Statements
Calcium and Osteoporosis and calcium, vitamin D, and osteoporosis <i>(21 CFR 101.72)</i>	For calcium and osteoporosis claim-high in calcium For calcium, vitamin D and osteoporosis claim-high in calcium and vitamin D -assimilable (Bioavailable) Supplements must disintegrate and dissolve, and Phosphorus content cannot exceed calcium content	The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis. The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate	Calcium and Osteoporosis: Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis. Calcium, vitamin D and osteoporosis: Adequate calcium and vitamin D, as part of a well balanced diet, along with physical activity, may reduce the risk of osteoporosis.

Qualified Health Claims

- **“Qualified Health Claims”** - SSA standard was successfully challenged on First Amendment grounds in *Pearson v. Shalala* (D.C. Cir. 1999) and subsequent litigation.
 - When a health claim petition shows that the claim is supported by “credible” evidence, FDA issues a letter of enforcement discretion for the claim under defined conditions.

Qualified Health Claim Criteria for FDA Enforcement Discretion

<p>Walnuts & Heart Disease</p> <p><i>Docket No. 2002P-029</i> 03/09/2004 enforcement discretion letter</p>	<p>Whole or chopped walnuts</p>	<p>Walnuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4).</p> <p>Walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber.</p> <p>The disclosure statement about total fat content (i.e., See nutrition information for fat content) is placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.</p>	<p>Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content.</p> <p>Notes: The bracketed phrase "and calorie" is optional in that FDA does not intend for the presence or absence of such phrase to be a factor in whether it considers enforcement discretion for the use of the qualified health claim. FDA considered this additional information beneficial to consumers to heighten their awareness of the caloric contribution from walnuts and encourages companies to include it in product labeling.</p>
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Notified Health Claims

- “Notified Health Claims” pursuant to FDAMA: Claim relies on an “authoritative statement” published by a “scientific body of the U.S. government with official responsibility for public health protection or research directly relating to nutrition” and represents the statement accurately in the context of a healthy diet.
- Notification filed 120 days before first introduction of a labeling claim for the food. Unless FDA objects, claim is permissible.

Notified Health Claims Based on Authoritative Statement of Scientific Body

<https://www.fda.gov/food/food-labeling-nutrition/fda-modernization-act-fdama-claims>

- Peanut allergy (introduction allergenic foods)
- Fluoride and the risk of dental caries
- Potassium and the risk of high blood pressure and stroke
- Sat. fat, cholesterol, and trans fat and the risk of heart disease
- Substitution of Sat. Fat with Unsat. fat and risk of heart disease
- Whole grain foods and the risk of heart disease and certain cancers

Health Claims vs. Dietary Guidance

- Dietary guidance statements focus on general dietary patterns, practices, and recommendations that promote health.
- They may refer to either a food substances of a disease or health related condition but not both:
 - Diets rich in fruit and vegetables may reduce the risk of coronary heart disease.
 - Drink low-fat milk for a healthy diet.

POLL:

Which statement is consistent with the law?

1. Packed with antioxidants to prevent Alzheimer's disease
2. Packed with antioxidants to help with your memory when you get old
3. Antioxidants to support your brain

MARKETING CLAIMS: NATURAL, ORGANIC, GLUTEN-FREE

When can natural claims be used?

- Ask the consumer (plaintiff attorney) ☺...
- Term not defined.
- Natural Claims (“Natural,” “All Natural,” “Made With Natural” Ingredients, “Made From Natural” Source (plant or animal), “no artificial . . .”).
- FDA Policy: will “not restrict the use of the term ‘natural’ except for added color, synthetic substances, and flavors . . .” 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993)(citing “natural flavor” definition as guideline for permissible sources and processing methods).
- USDA/FSIS limits “natural” claims to foods containing no artificial flavor, color, chemical preservative, or other artificial or synthetic ingredients and are not more than “minimally processed.”
- Much litigation.

Long-Pending FDA Evaluation

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA-2014-N-1207]

**Use of the Term “Natural” in the
Labeling of Human Food Products;
Request for Information and
Comments**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notification of request for
comments.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the establishment of a docket to receive information and comments on the use of the term “natural” in the labeling of human food products, including foods that are genetically engineered or contain ingredients produced through the use of genetic engineering. We are taking this action in part because we received three citizen petitions asking that we define

- Response to 3 Citizen Petitions and requests from Federal courts in false advertising cases involving “natural” claims
- FDA requested comment on whether & how FDA should define “natural”
- 80 FR 69905 (Nov. 12, 2015)
- Will there ever be a regulation?

Organic Claims

- Organic Foods Production Act of 1990 and NOP (AMS) implementing regulations 7 C.F.R. Part 205.
- Uniform standard regarding production and handling of organically produced agricultural products
- Requires third-party certification by USDA accredited certifiers
- Organic claims are prohibited for food ingredients produced using “excluded methods”:
 - Synthetic fertilizers, pesticides, or herbicides
 - Genetically engineering
 - rDNA, cloning, etc.
 - Sewage sludge
 - Ionizing radiation
- National List



Organic Claims

Four categories of labeling:

- 100% organic: Excluding salt and water 100% organic, may use seal.
- Organic: At least 95% organically produced ingredients, remaining 5% on National List.
- Made with organic: Contains at least 70% organic ingredients.
- Less than 70%: Identify organic ingredients in ingredient statement and may include organic percentage on information panel.

Gluten-Free



21 C.F.R. § 101.91

Less than 20 ppm gluten (i.e., a threshold, “free” is not free), BUT:

- May not contain a “gluten-containing grain” (any species of wheat, rye, barley, or any of their crossbred hybrids, such as triticale), even if the product contains less than 20 ppm
- May not contain an ingredient that is derived from a gluten-containing grain that has not been processed to remove gluten, such as wheat flour
- If any gluten is present in the food, that presence must be unavoidable and the gluten must be below 20 ppm

Gluten-Free

- Regulation allows labeling gluten content, i.e., “gluten-free, less than 10 ppm gluten.”
- Free is not free. 20 ppm is analytical limit.
- For fermented products, the gluten content of the raw materials before fermentation; if they contain more than 20 ppm gluten or gluten-containing cereals, fermented product may not be labeled gluten-free.
- A product may be gluten-free but still require allergen warning for wheat, e.g., wheat starch (specially processed to remove gluten).

QUESTIONS?

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