

CLAIMS REGULATION: US FDA

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Seminar on Nutrient & Health Claims of Food Products
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Decernis:

Research + Systems for Global Compliance

- Focus: Food, Consumer- and Chemical Product Compliance
- 90,000 Regulations, 210 Countries, 16 Economic Areas
- 40 languages, 5 million synonyms & identifiers

PRODUCTS & SERVICES

- Reference
- Horizon Scanning
- Formulation Compliance Analysis (**Red Light/Green Light**)
- Supply Chain Compliance Management
- Market Entry Reports & Translations

Methodology



Landscape

Recipes/Lists

Analysis

Certificates

Bypasses



KKENNY

Q Landscape analysis

Module

CLAIMS

Usage

Type to search...

Claim Type

NUTRIENT - FREE OR ZERO X

NUTRIENT - HIGH IN - INCREASED X

NUTRIENT - LOW - REDUCED X

NUTRIENT - REFERENCE VALUES X

NUTRIENT - SOURCE OF X

Countries

UNITED STATES X

Add ingredients from recipe

SELECT RECIPE...

Report Type

TABULAR REPORT

Identifier

NAME

Ingredient

Type & press enter to search...

X CLEAR FORM

▶ RUN ANALYSIS

Methodology

Secure | https://formula.decernis.com/landscape/analyze?module_id=10&country=United%20States&reportType=tabular&function=2784&function=2785&function=2786&function...

Apps Metrics Mercosur Normativa Piano SSM Netflix GCP Courses Heiway G_Translate Chemical Watch gComply gComplyPlus gC+ 4.0 Decernis News D_ProjMgt D_Projects

DECERNIS U.S. Patent 7,769,712 B2 Landscape Recipes/Lists Analysis Certificates Bypasses

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Landscape analysis

MATRIX TABULAR PDF XLS

Name	DID	CAS	Function	Usage	Country	Result indicator	Threshold	Comments	Citation
Type to filter...	Type to filter...	Type to filter...	Type to filter...	Type to filter...	Type to filter...	Type to filter...	Type to filter...	Type to filter...	Type to filter...
Antioxidants (ALL)	10000315	119-13-1, 14101-61-2, 1721-51-3, 25612-59-3, 303-98-0, 490-23-3, 50-81-7, 7616-22-0, 84775-52-0	Nutrient - Free or Zero	FoodStuffs	United States	RESTRICTED	--	Butter	21 CFR 101.67. Use of nutrient content claims for butter - Claims
Antioxidants (ALL)	10000315	119-13-1, 14101-61-2, 1721-51-3, 25612-59-3, 303-98-0, 490-23-3, 50-81-7, 7616-22-0, 84775-52-0	Nutrient - Free or Zero	FoodStuffs	United States	RESTRICTED	--	Butter	21 CFR 101.67. Use of nutrient content claims for butter - Claims
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Antioxidants (ALL)	10000315	119-13-1, 14101-61-2, 1721-51-3, 25612-59-3, 303-98-0, 490-23-3, 50-81-7, 7616-22-0	Nutrient - High in - Increased	FoodStuffs	United States	REQUIRED	≥ 100 % RDI per RACC	Foodstuffs	21 CFR 101.54. Nutrient claims for good source, high, more, and high potency - HealthClaims

Key Abbreviations

- US Federal Food Drug Cosmetics Act (FDCA)
- Nutritional Labeling and Education Act (NLEA)
- Dietary Supplement Health and Education Act of 1994 (DSHEA)
- Code of Federal Regulations (CFR)
- Reference Daily Intake (RDI)
- Daily Reference Value (DRV)
- Reference Amount Customarily Consumed (RACC)

US Definition of Food (21 U.S.C. § 321)

Any substance, whether:

- Processed, semi-processed or raw intended for human consumption
- Includes drinks, chewing gum
- Or, used in the manufacture, preparation or treatment of food.
- DSHEA defines dietary supplements as a category of food. However, different rules apply for supplements (Supplement Facts) vs. conventional foods (Nutrition Facts)

Types of Claims FDA Regulates

- **Nutrient Content Claims**

- “Milk is a good source of calcium.”

- **Health Claims**

- “Calcium-rich foods such as yogurt may reduce the risk of osteoporosis.”

- **Qualified Health Claims**

- “Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.”

- **Structure-Function Claims**

- “Calcium builds strong bones.”

21 CFR §101.13 Nutrient Content Claims: Definitions

- **Nutrient Content Claim:** directly or by implication characterizes the level of nutrient in a food or supplement (e.g., "low fat," "high in oat bran," or "contains 100 calories").
- **Express Claims:** “any direct statement about the level (or range) of a nutrient in the food, e.g., “low sodium” or “contains 100 calories.”
- **Implied Claims:** absence or presence of ingredient in a certain amount (high in oat bran) or “Healthy.”
- **Relative Claims:** compares nutrient value of one food to another food: “25% less sodium than regular potato chips.”

Nutrient Content Claims – which dietary ingredients?

~~omega-3 fatty acids~~

biotin

calcium

chloride

cholesterol

choline

chromium

copper

dietary fiber

folate

iodine

iron

magnesium

molybdenum

niacin

pantothenic acid

potassium

riboflavin

saturated fat

selenium

sodium

sugars

thiamin

total calories

total fat

vitamin A

vitamin B6

vitamin B12

vitamin C

vitamin D

vitamin E

vitamin K

zinc

21 CFR: Specific Permitted Nutrient Content Claims

- §101.54(b) **High/Rich in/Excellent Source of** $\geq 20\%$ of RDI
- §101.54(c) **Good Source/Contains/Provides** 10-19% of RDI
- §101.54(e) **More/Fortified/Enriched/Added/Extra/Plus** $\geq 10\%$ of RDI
- §101.54(f) **High Potency** $\geq 100\%$ of RDI
- §101.54(g) **Antioxidant** RDI + Scientific Evidence + Named Nutrients

21 CFR: Specific Permitted Nutrient Content Claims

- §101.56 **"Light" or "Lite" claims**
- §101.60 **"Calorie or Sugar" claims**
- §101.61 **"Sodium or Salt" claims**
- §101.62 **"Fat, fatty acids, and cholesterol" claims**
- §101.65 **Implied nutrient content claims**
- §101.65(d) **"Healthy" claims**
- §101.67 **Butter claims**

21 CFR: Specific Permitted Nutrient Content Claims

Type	CFR Reference	Claim	Requirement
Calories	21 CFR 101.60(b)	Free:	<5 calories per Reference Amount Customarily Consumed (RACC) and serving
		Low:	≤40 calories per RACC or per 50g if RACC is small ≤120 calories for meals or entrees
		Reduced /Less:	At least 25% less calories per RACC than reference food
Sugar	21 CFR 101.60(c)	Free:	<0.5 mg sugar per RACC and serving or per serving for meals and main dishes
		Low:	Claim not defined and therefore not permitted
		Reduced /Less:	At least 25% less sugar per RACC (per 100 g for meals and main dishes) than reference food
Sodium	21 CFR 101.61	Free:	<5 mg sodium per RACC and serving or per serving for meals and main dishes
		Low:	≤140 mg (35 mg for "Very Low") sodium per RACC or per 50g if RACC is small ≤140 mg sodium per 100 g for meals and main dishes
		Reduced /Less:	At least 25% less sodium per RACC (per 100 g for meals and main dishes) than reference food

21 CFR: Specific Permitted Nutrient Content Claims

Type	CFR Reference	Claim	Requirement
Total Fat	21 CFR 101.62(b)	Free:	<0.5g fat per RACC and serving
		Low:	≤3g per RACC or per 50g if RACC is small ≤3g per 100g and ≤30% calories from fat for meals and entrees
		Reduced /Less:	At least 25% less fat per RACC (or per 100g for meals and entrees) than reference food
Saturated Fat	21 CFR 101.62(c)	Free:	<0.5g saturated fat and <0.5g trans fat per RACC and serving
		Low:	<1g saturated fat per RACC and ≤15% calories from saturated fat ≤1g saturated fat per 100g and ≤10% calories from saturated fat for meals and entrees
		Reduced /Less:	At least 25% less saturated fat per RACC (or per 100g for meals and entrees) than reference food
Cholesterol	21 CFR 101.62(d)	Free:	Less than 2 mg cholesterol per RACC and serving or per serving for meals and main dishes
		Low:	≤20 mg cholesterol per RACC or per 50g if RACC is small; ≤20 mg cholesterol per 100 g for meals and main dishes
		Reduced /Less:	At least 25% less cholesterol per RACC (per 100 g for meals and main dishes) than reference food

Note: Cholesterol claims not permitted if food contains >2g saturated fat

Nutrient Content Claims – Specific Prohibitions

ALA, DHA and EPA omega-3 fatty acids

- **Used to have valid Nutrient Content Claims**
- **April 28, 2014 (79 FR 23262)** “Food Labeling: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids”
- New regulation **prohibits** claims that product is "high in" DHA or EPA. Synonyms, such as "rich in" and "excellent source of," also prohibited – applies to both foods and dietary supplements
- FDCA allows nutrient content claims only if reference level for claim has been established. No RDI or DRV set for DHA, EPA or ALA.
- **Guidance on omega-3 fatty acids:**
<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM484251.pdf>

Nutrient Content Claims – Specific Prohibitions

- **ALA, DHA and EPA omega-3 fatty acids:**
- Rule prohibits all DHA and EPA nutrient content claims
- However limited ALA Claims are still permitted:

Nutrient Content Claim for ALA	Conditions for Making Such a Claim
"High"	≥ 320 mg of ALA per reference amount customarily consumed (RACC) (≥ 20% of 1.6 g/day)
"Good Source"	≥ 320 mg of ALA per reference amount customarily consumed (RACC) (≥ 20% of 1.6 g/day)
"More"	≥ 160 mg of ALA more per RACC than an appropriate reference food (≥ 10% of 1.6 g/day)

Nutrient Content Claims – Small Business Guidance

- [Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims](#) (August 20, 2003)
- [Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods](#) (July 2008)
- [Guidance for Industry: Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids; Small Entity Compliance Guide](#) (February 2016)
- [Guidance for Industry: Gluten-Free Labeling of Foods](#) (June 2014)

21 CFR §101.13

Nutrient Content Claim Notifications

- **Nutrient content claims are approved for use on all food products, except those intended for children and infants who are under two years old.**
- **Baby foods and formulas have their own, separate regulations.**

Health Claims

- Definition = express or implied statement in food labeling about relationship of a food substance to a disease or health-related condition.
- Not just “any claim about health”
- Substance can be a specific food (tomato) or a component of food (lycopene), whether in conventional food or dietary supplement form
- Requires pre-approval by FDA

Subject of a Health Claim

- Causal relationship between a substance and a disease or health-related condition for the general U.S. population or a subpopulation (e.g., women, elderly)
- Claims ability to reduce the risk of disease.

Not treat, prevent, cure or mitigate

→ Drug

21 CFR §101.14

Health Claims for food and dietary supplements

(a)(1) Health claims are defined as all explicit or implicit statements that suggest a relationship between the presence a substance and a **disease** or **health-related condition**.

(d)(1) When FDA determines that a health claim meets the validity requirements based on scientific agreement, it issues a regulation to Subpart E authorizing the health claim.

➤ **§ 101.70 Any interested person may petition FDA to issue a regulation regarding a health claim.**

Authorized Health Claims – Subpart E

- Section 101.72 : Calcium, Vitamin D, and **osteoporosis**.
- Section 101.73 : Dietary fat and **cancer**.
- Section 101.74 : Sodium and **hypertension**.
- Section 101.76 : Fiber-containing grain products, fruits/vegetables and **cancer**.
- Section 101.78: Fruits/vegetables and **cancer**.
- Section 101.79: Folate and **neural tube defects**.
- Section 101.80 : Dietary noncarcinogenic carbohydrate sweeteners and **dental caries**.

Authorized Health Claims – Subpart E

Risk of Coronary Heart Disease (CHD)

- Section 101.75: dietary **saturated fat** and **cholesterol** and **heart disease**.
- Section 101.77: fruits, vegetables, and grain products that contain fiber and risk of **heart disease**.
- Section 101.81: Soluble fiber from certain foods and risk of **heart disease**.
- Section 101.82: Soy protein and risk of **heart disease**.
- Section 101.83: plant sterol/stanol esters and risk of **heart disease**.

21 CFR §101.14

Health Claims

Health claims authorized in this section do not apply to:

- (1) **Infant formulas** subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and
- (2) **Medical foods** defined by section 5(b) of the Orphan Drug Act.

Qualified Health Claims

- Qualified Health Claims are based on scientific evidence that is credible but that does not meet the SSA standard
- Include qualifying language to prevent consumers from being misled about the level of support for the claim
- Considered under FDA's exercise of enforcement discretion
(e.g. **not explicitly authorized by regulation**).

Guidance:

[Guidance for Industry: FDA's Implementation of "Qualified Health Claims"](#)

Qualified Health Claims - Examples

- **QHCs: Cancer**

- Calcium and colon/rectal cancer
- Green tea and breast/prostate cancer
- Selenium and site-specific cancers
- Antioxidant vitamins and certain cancers
- Tomato and/or Tomato Sauce and certain cancers

- **QHCs: Heart Disease**

- Nuts
- Walnuts
- Omega 3 fatty acids (EPA/DHA)
- Monounsaturated fatty acids from olive oil
- Unsaturated fatty acids from corn oil
- B vitamins and vascular disease

Qualified Health Claims – Example Claim Statements

- “Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim.”
- “Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive.”
- “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.”
- “Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease.”

Structure/Function Claims

- Describe role of nutrient or dietary ingredient intended to affect normal structure or function in humans (“calcium builds strong bones”);
- Describe role of nutrient or functional component indicating that the food/supplement sustains **normal growth, metabolism and general well-being**
- **Different from disease claims!** (e.g. cures cancer). A structure/function claim must not include a disease term
 - ✓ If label of product marketed as dietary supplement bears disease claim, product will be subject to regulation as drug unless claim is authorized health claim for which product qualifies (21 CFR 101.14 Subpart E).
- No specific regulation but see guidance:
 - [Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide](#)

Structure/Function Claims for Foods vs. Supplements

- S/F claims for conventional **foods** focus on **effects derived from nutritive value**
- S/F claims for **dietary supplements** may focus on **non-nutritive as well as nutritive effects**.
- FDA is likely to interpret dividing line between structure/ function claims and disease claims in a similar manner for conventional foods as for dietary supplements.
- **FDA** does *not* require conventional food manufacturers to notify FDA about their S/F claims + disclaimers not required for conventional foods S/F claims.
- For **USDA**-regulated food products (only), such claims are subject to pre-approval process.

Structure Function Claims for Dietary Supplements require Notification

- The FDCA requires that those who wish to market a dietary supplement notify FDA regarding labeling of its product, pursuant to § 403(r)(6) of FDCA.
- FDCA states that dietary supplement may bear certain statements on label or in its labeling:
 - if the claim(s) meets certain **requirements**
 - if entities making claims have **substantiation** that such statement is truthful and not misleading, and if
 - **disclaimer** prominently displayed on the label.
- Dietary supplements must include **standard disclaimer**: FDA has not evaluated the claim and supplement is not intended to "diagnose, treat, cure or prevent any disease" Foods do not need this disclaimer statement.
- **Finally, notification must be submitted to FDA no later than 30 days after first marketing of dietary supplement product.**

Dietary Supplements vs. Foods

- Congress defined "dietary supplement" in Dietary Supplement Health and Education Act (DSHEA) of 1994.
- Dietary supplements can be extracts or concentrates and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids, or powders.
- Can also be in other forms, **such as a bar**, but if so, label must not represent product as conventional food.
- Whatever the form, **DSHEA places dietary supplements in special category under general umbrella of "foods," not drugs, but requires that every supplement be labeled as dietary supplement.**

New Dietary Ingredients

- Dietary Supplement Health and Education Act (DSHEA) of 1994 defines "new dietary ingredient" as components of dietary supplements not sold in US as dietary supplement before 15 Oct 1994.
- In case of new dietary ingredient use, manufacturer must demonstrate to FDA why ingredient is reasonably expected to be safe for use in dietary supplement, unless it has been recognized as a food substance and is present in the food supply.
 - **There is no authoritative list of dietary ingredients that were marketed before 15 Oct 1994.** Manufacturers and distributors are responsible for determining if dietary ingredient is "new", and if it not, for documenting that dietary supplements containing the dietary ingredient in question were marketed before 15 Oct 1994.

Claim Substantiation

- FDCA Section 403(r)(6) requires manufacturer of dietary supplement making a nutritional deficiency, structure/ function, or general well-being claim to have substantiation that claim is truthful and not misleading.
- FDA created guidance with 21 specific examples to demonstrate substantiation:

[Guidance for Industry Substantiation for Dietary Supplement Claims Made Under Section 403\(r\) \(6\) of the Federal Food, Drug, and Cosmetic Act](#)

Claims Substantiation Example

“promotes weight loss”

- Dietary supplement contains various vitamins and minerals and botanical extract.
- Manufacturer relies on randomized controlled double blind clinical study showing that subjects who took botanical extract had small but significant increase in metabolism over subjects taking placebo over 24-hour period.
- However, if study did not examine **effect of extract on subjects' weight**, then no actual research demonstrates that short term increase in metabolism will actually translate into any measurable weight loss.
- **Weight loss claim not adequately substantiated.**

Claims Substantiation Example

“improves cognitive abilities”

- Manufacturer develops dietary supplement to improve memory and cognitive ability and intends to market the product to parents for their **school-aged children**.
- Manufacturer relies on several high quality clinical studies which examine ingredient's effect in **elderly people** with diagnosed, age-related memory problems.
- Studies would not be adequate substantiation for claim about memory improvement in **young children** because patient population (elderly people with memory problems) is completely different from intended population (children) in claim.
- **Claim not adequately substantiated.**

Descriptive and Organic Claims

- FDA outlines requirements for **descriptive claims** which are neither nutrient content claims nor health claims in [21 CFR Subpart F 101.91-95](#). Specific descriptive claims include: “gluten free”, “fresh”, “frozen”, “freshly frozen” and “frozen fresh”.
- [Organic 7 CFR 205 Subpart D](#) – Labels, Labeling and Market Information,
 - Both FDA and USDA food products subject to regulation by USDA Agricultural Marketing Service (AMS) and National Organic Standards Board (NOSB). “**Organic**” defined in the negative, i.e. absence of preservatives, artificial colors, other artificial ingredients.
 - Four labelling categories based on product composition and labeling specifications.

“Natural” Claims

- FDA: No regulation but does provide guidance:
 - [What is the meaning of 'natural' on the label of food?](#) FDA “has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.”
 - See also [Warning Letter to Alexia Foods, Inc 11/16/11](#) FDA “considers use of the term “natural” on a food label to be truthful and non-misleading when “nothing artificial or synthetic...has been included in, or has been added to, a food that would not normally be expected to be in the food.” [58 FR 2302, 2407, 6 Jan 1993].”
- **“Natural”** - USDA has defined criteria for “Natural” as stated in the FSIS [Food Standards and Labeling Policy Book](#).
- Both FDA and USDA have been petitioned to establish regulations.

Comparison: Nutrition Claims

Country/ Region	Definition	Date of Regulation
CODEX (CAC/GL 23-1997)	Nutrition claim means any representation which states, suggests or implies food has particular nutritional properties including e.g., energy value, content of protein, fat and carbohydrates, as well as content of vitamins and minerals. (Nutrient content claims, Nutrient comparative claims, Non-addition claims)	Revised 2004 Last Amended 2013.
Australia/New Zealand (Standard 1.2.7)	Claims about specified food properties with specific conditions and qualifying criteria listed in Standard, e.g., vitamins, minerals, protein, dietary fibre, fat and components of fat. Claims using certain descriptors (e.g., 'low', 'high', 'reduced', 'increased') permitted only for food properties listed in Standard. Certain claims (e.g., 'source of') about food properties not listed in Standard are permitted.	Mar 2016 (effective 12 Nov 2017)
EU (EC 1924/2006)	Conditions for nutrition claims listed in EC Regulation 1924/2006. Use of descriptors restricted: For example 'high' only permitted for fibre, protein, vitamins, minerals and fatty acids.	20 Dec 2006 Last Updated 5 July 2017
Canada (CFIA Website)	Only claims listed in the regulations are permitted.	Last Updated 3 Mar 2017
United States (FDA website)	Only claims listed in regulations are permitted. Accurate quantitative statements may also be used, such as 'contains X grams of omega-3 fatty acids per serving'.	Updated 11 Apr 2016

Comparison: Health Claims

<p>CODEX (CAC/GL 23-1997)</p>	<p>Health claim means any representation that states, suggests or implies relationship exists between food/constituent of food and health. Include: Nutrient function claims, Other function claims, and Reduction of disease risk claims.</p>	<p>Revised 2004 Last Amended 2013.</p>
<p>Australia/New Zealand (Standard 1.2.7)</p>	<p>Food-health relationship underpinning health claim must be either pre-approved by FSANZ or self-substantiated. Pre-approved food-health relationships listed in Standard along with conditions and qualifying criteria. Standard includes >200 pre-approved food-health relationships that can be used to support general level health claims. Two categories of health claims: general level health claims and high level health claims (referring to a serious disease or biomarker of serious disease).</p>	<p>Mar 2016 (effective 12 Nov 2017)</p>
<p>EU (EC 1924/2006)</p>	<p>Claims permitted only if gazetted / included in EC Register of Nutrition and Health Claims made on Foods'. Register contains 261 authorized claims (2,058 non-authorized!).</p>	<p>20 Dec 2006 Last Updated 5 July 2017</p>
<p>Canada (CFIA Website)</p>	<p>Two types of function claims not considered drug claims: (1) 'Nutrient function' claims expressly permitted in regulations. (2) 'Non-nutrient function' claims not expressly prohibited if truthful and not misleading. 'General level' claims also permitted (do not refer to specific health effect, disease or health condition, but includes dietary guidance).</p>	<p>Last Updated 3 Mar 2017</p>
<p>United States (FDA website)</p>	<p>If mentions disease or health-related condition, classified as health claim, not structure/function claim. Listed authorized claims can be made without pre-approval but should not be false or misleading. Guidance for industry available.</p>	<p>Updated 11 Apr 2016</p>

Thank you!

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