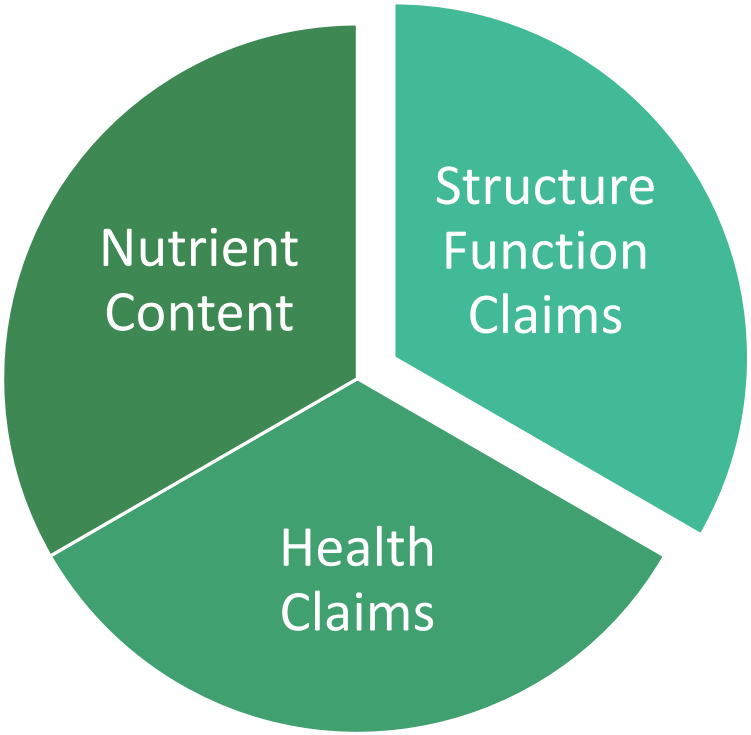
Nutrition Claims

Types of Nutrition Claims



Individual Food

All foods that don't meet the main dish or meal requirements

Typically a single food group

- May be more than 1 food group

Includes

- Snacks
- Breads
- Cheeses

In many cases have different nutrition claim requirements

21CFR101.13

Main Dish

Can come in single serve or multi-serve packages

Contain not less than 2 - 40 g servings from the following food groups

- Bread, cereal, rice, and pasta
- Fruit and vegetable
- Milk, yogurt and cheese
- Meat, poultry, fish, dry beans, eggs and nuts

May not be a sauce, condiments, relishes, pickles, jams, jellies, syrup, breading, a dessert, or a beverage

- Allowed as part of the product or in the photo on package

21CFR101.13

Meal

Contain at least 10 oz per serving

Contain not less than 3 - 40 g servings from the following food groups

- Bread, cereal, rice, and pasta
- Fruit and vegetable
- Milk, yogurt and cheese
- Meat, poultry, fish, dry beans, eggs and nuts

May not be a sauce, condiments, relishes, pickles, jams, jellies, syrup, breading, a dessert, or a beverage

- Allowed as part of the product or in the photo on package

21CFR101.13

Substitute Vs Imitation

SUBSTITUTE

Interchangeable with another food

- Flavor
- Physically
- Functionally

Not nutritionally inferior

Must list difference from original products

- Not recommended for frying

IMITATION

Nutritionally inferior to original food

May contain ingredients not normally found in original product

21CFR101.13

Industry Practice

Design products to meet desired requirements

- Meal or individual food
- Claim requirements

Small RACC and Serving Size

If serving size is less than 50 g

Claims must be made on a 50 g basis

For positive claims

- Good, excellent
- Must meet claim on serving size

For negative claims

- Low, no, lite, free
- Must meet claim on 50 g basis

Nutrient Content Claims

Defined the amount of a nutrient in the food

Examples

- High, Good, Low, No

Must meet specific requirements

Disclosure statement

- 13 g fat, 4 g sat fat, 480 mg sodium, 60 mg cholesterol
- Main dish and meals have different disclosure levels

Disclosure Level

	Individual Foods	Main Dish	Meal
Fat	13	19.5 g	26 g
Sat Fat	4 g	6 g	8 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

21CFR101.13

Nutrition Comparative Claims

Appropriate reference food

- A food the could reasonable be substituted for the food with the claim
- Examples
  - Reduced Soy Sauce vs Soy Sauce
  - Reduced Salt Potato Chips vs Potato Chips

Appropriate Reference Foods

Original Food	Reference Food	Are they appropriate?
Mayo	Reduced Fat Mayo	
Potato Chips	Popcorn	
Snack Crackers	Potato Chips	
Sour Cream Based Dip	Salsa	
Meat Snack (Jerky)	Snack Crackers	
Cereal	Potato Chips	

Calorie Free

Less than 5 calories per RACC and labeled serving

21CFR101.60

Low Calories

40 calorie or less per RACC (and 50 g serving if RACC is small)

Meals and Main Dish

- 120 calories or per 100 g

21CFR101.60

Reduced Calories

25% fewer per RACC than appropriate reference food

Meals and Main Dish

- 25% fewer calories /100 g

Reduced calories claims can’t be used on foods the meet low calories

Light

If more than 50% of calories per fat
- Fat must be reduced by 50% per RACC

If less than 50% of calories from fat
- Fat must be reduced by 50% per RACC
- Calories must be reduced by 1/3

Meal or Main Dish
- Must meet low calorie
- Must meet low fat

21CFR101.56

Fat

Fat Free

Low Fat

Light

Lean

Were very popular when NLEA was first implemented

Require Mono and Poly fats in nutrition facts panel

Disclosure as required

Fat Free

Less than 0.5 g per RACC and serving size

Meals or main dish

- Less than 0.5 g per labeled serving

No ingredients that are understood to be fat

- Must label * adds a trivial amount of fat

Low Fat

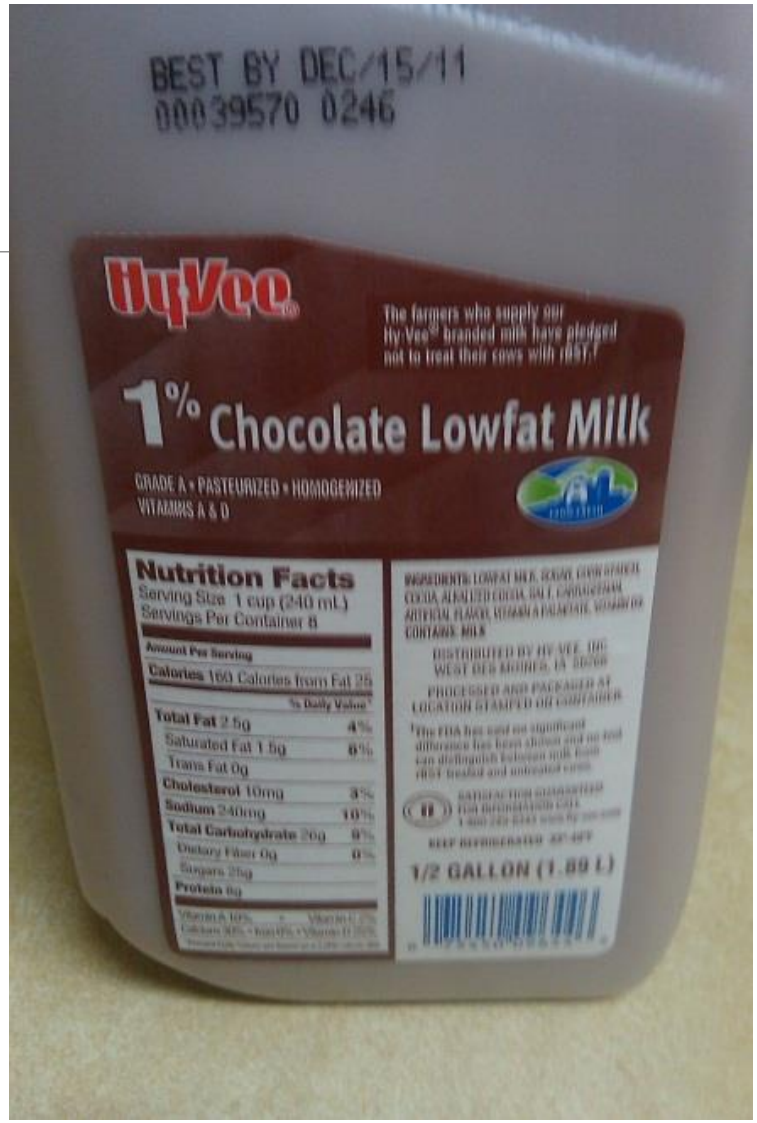
Less than 3 g of fat per RACC and 50 g serving if RACC is small

Meal and Main Dish

- Less than 3 g per 100 g
- Not more than 30% of calories from fat

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62



Reduced Fat

At least 25% less the RACC than an appropriate reference food

Meals or Main Dish

- Less than 25% per 100 g

Reference food may not be low fat

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Percent Fat Free

May be used if product meets low fat

100% Fat Free must meet fat free

Must meet low fat to use

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

USDA

Lean

Seafood or Game Products

- Per RACC and 100 g
- 10 g total fat
- 4.5 g sat fat
- ≤ 95 mg cholesterol

Meal and Main Dish

- < 8 g total fat
- 3.5 g sat fat

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

USDA Lean

Less than 10 g fat

Less than 4.5 g of sat fat

Less than 95 mg of cholesterol

Per RACC and 100 g

Main Dish or Meal

- Per 100 g and labeled serving

Extra Lean

Seafood or game meat products

- < 5g total fat
- < 2g saturated fat
- < 95mg cholesterol per RACC and per 100g

Meals and main dishes,

- meets criteria per 100g and per labeled serving

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

USDA Extra Lean

Less than 5 g of fat

Less than 2 g of sat fat

Less than 95 mg of cholesterol

Per RACC and 100 g

Main dish and meal

- Per 100 g and labeled serving

Sat Fat Free

Less than 0.5 g sat fat and less than 0.5 g trans fat per RACC and serving size

Meal and Main Dish

- Less than 0.5 g sat fat and less than 0.5 g trans fat per labeled serving

Contains no ingredients understood to contains sat fat

- Labeled * adds a trivia amount

Must include next to claim

- Cholesterol if more than 2 mg/RACC
- Fat is more than 3 g/RACC
- For meals and main dish per labeled amount

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Low Sat Fat

1 g or less of sat fat per RACC

15% or less of calories from sat fat

Meal or Main Dish

- 1 g or less per 100 g
- 10% or less of calories from sat fat

Must include next to claim

- Cholesterol if more than 2 mg/RACC
- Fat is more than 0.5 g/RACC
- For meals and main dish per labeled amount

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Reduced Sat Fat

At least 25% less sat fat per RACC than an appropriate reference food

Meals and Main Dish

- At least 25% less sat fat per 100 g

Reference food may not meet low sat fat

Must include next to claim

- Cholesterol if more than 2 mg/RACC
- Fat is more than 3 g/RACC
- For meals and main dish per labeled amount

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Trans Fat

Claims are not codified

Companies state the amount of trans fat

Requires are like fat claims

- Must be 0 g to make claim
- Include Mono and Poly unsaturated fats in nutrition facts panel
- Declare disclosure if needed

Cholesterol Free

Less than 2 mg per RACC and per labeled serving

Meals and Main Dish
- 2 mg per labeled serving

Contains no ingredients known to contain cholesterol
- * Contains a trivial amount

Claim is only allowed if
- Sat fat 2 g or less per RACC
- For meals and main dish per labeled serving

Must declare values next to claim when exceed disclosure

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Low Cholesterol

20 mg or less per RACC or 50 g serving is RACC is small

Meal or Main Dish

- 20 mg per 100 g

Claim is only allowed if

- Sat fat 2 g or less per RACC
- For meals and main dish per 100 g

Must declare values next to claim when exceed disclosure

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Reduced Cholesterol

At least 25% less cholesterol per RACC than appropriate reference food

Meals and Main Dish

- 25% less cholesterol per 100 g

Reference food may not be low cholesterol

Must declare values next to claim when exceed disclosure

Requires mono and poly fats in nutrition facts when claim is made

21CFR101.62

Omega 3

Mono and Poly unsaturated fats

Believed to have some health benefits

Three types

- ALA
- DHA
- EPA

FDA issued a interim final rule

- No generic Omega 3 claims
- No DHA or EPA claims
- Enforcement discretion on ALA claims

Sodium

Currently average American consumer approximately 3500 mg/day

- RDI is 2300 mg/day

Dietary Guidelines encourage less sodium

- Changed the RDI to 1500 mg/day for adults over 50

National Salt Reduction Imitative

- Reduce sodium by 20% in 5 years
- Companies signed on to reduce sodium
- Kraft, Heinz, Campbell, Mars, Subway, Target

Many companies are doing this quietly without claims

Sodium Free

Less than 5 mg per RACC and labeled serving

Meal and Main Dish

- Less than 5 mg per labeled serving

Contains no ingredients that are generally accepted to contain sodium

- *Adds a trivia amount

Salt Free must meet sodium free

- Does not speak to potassium chloride or other salts

21CFR101.61

Very Low Sodium

Less than 35 mg of sodium per RACC or 50 g serving is RACC is small

Meal and Main Dish

- 35 mg per 100 g

21CFR101.61

Low Sodium

Less than 140 mg per RACC or 50 g if RACC is small

Meals and Main Dish

- 140 mg per 100 g

21CFR101.61

Light Sodium

Light may be used with 50% sodium reduction

Light in combination with

- Low calorie with 50% sodium reduction
- Low fat with 50% sodium reduction

Meals and Main Dish

- Must be low sodium

Lightly Salted

- 50% sodium reduction than reference food
- Can‘t be a low sodium food

21CFR101.56 and 21CFR101.61

No Salt Added

If does not meet sodium free

- Use “This is not a sodium free food” adjacent on panel

21CFR101.61

Fiber

Fiber claims have gained popularity
Dietary Guidelines state American diet lacks fiber
Good Source - > 10% DV
Excellent Source > 20% DV
If food is not low fat requires total fat disclosure

Sugar Free

Less than 0.5 g sugar per RACC and labeled serving

Meals and Main Dish

- Less than 0.5 g per labeled serving

Contains no ingredients generally understood to be sugar

- * Adds a trivial amount of sugar

If does not meet low calorie

- Must state “This is not a low calorie food”

Reduced Sugar

At least 25% less sugar than appropriate reference food

Meal and Main Dish

- At least 25% less sugar per 100 g

No Added Sugars

No added sugar

Added sugar definition

Sugar alcohols are allowed

Contains no ingredients generally understood to be sugar

- * Adds a trivial amount of sugar

Must state “not a low/reduced calorie food”

21CFR101.60

More Claims

10% more than the reference food

Used for
- Vitamins
- Minerals
- Protein
- Fiber
- Potassium

Other words
- Fortified
- Enriched
- Added
- Extra
- Plus

21CFR101.54

Vitamins and Minerals

More than 10% DV

- Good
- Contains
- Provides
- Similar

More than 20% DV

- High
- Rich
- Excellent
- Similar

21CFR101.54

Antioxidants

Nutrients that prevent oxidation in cells

FDA does not have a definition

Issued warning letters to define claims

Allows claims for defined antioxidants

Must include name of antioxidants with the claim

21CFR101.54

Protein

Claims are allowed but complicated

Protein DV is required if claims are made

Typically make

- Good Source more than 10% DV
- Excellent Source more than 20% DV
- X g protein (requires good source)

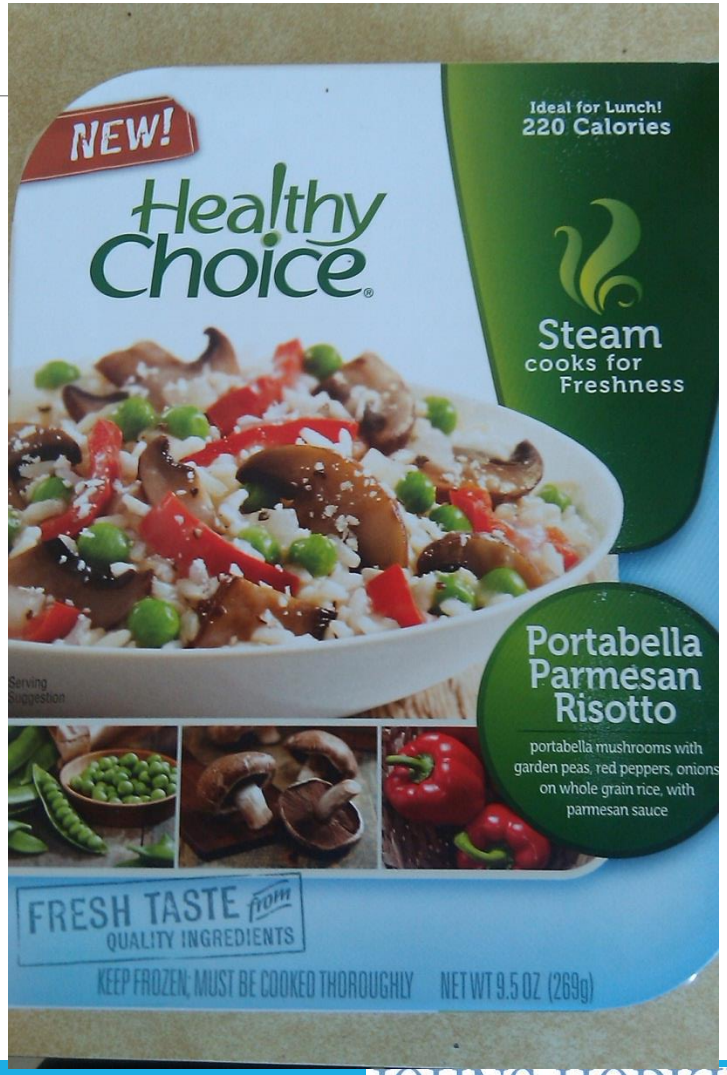
Protein DV is calculated based on protein quality

PDCAAS is used to determine protein DV

Healthy

	Individual Food	Seafood/Game Meat	Meal/Main Dish
Fat	Low Fat	< 5 g /RACC and Serving Size	Low Fat
Sat Fat	Low Sat Fat	<2 g/RACC and Serving Size	Low Sat Fat
Cholesterol	≤ disclosure level	< 95 mg/RACC & 100 mg	≤ 90 mg
Sodium	≤ 480 mg/ RACC or 50 g if RACC is small	≤ 480 mg/ RACC or 50 g if RACC is small	≤ 600 mg
Beneficial Nutrients	Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber except: raw fruits and vegetables; or a single ingredient or mixture of frozen or canned single ingredient fruits and vegetables (may include ingredients whose addition does not change the nutrient profile of the fruit or vegetable); enriched cereal-grain products that conform to a standard of identity in *21 CFR 136, 137, or 139*.	Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber	Contains at least 10% of the DV /l.s. of two nutrients (for a main dish product) or of three nutrients (for a meal product) of vit. A, vit. C, calcium, iron, protein, or fiber.
Fortification	Allowed per regulation	Allowed per regulations	Allowed per regulations

Brand Names



Brand names can be implied claims

Must meet label requirements

Diet

Exemption to allow on soft drinks marketed prior to 10/25/1989

Must comply with 105.66 and 101.13

USDA Claims Differences

When making a meal or main dish product must include the food

Example

- Broccoli is a good source of Vitamin C

Undefined Claims

Undefined nutrient content claims are not allowed

Examples

- Low Sugar
- Low Carb

Implied Nutrient Content Claims

Claims that make consumers believe the product meets a specific nutrition claim without using any words that a regulated

Examples

- Contains 3 g fat
- 0 g trans fat
- Good Source Oat Bran (fiber)
- Contains as much calcium as a glass of milk
- Health, healthful, healthier, healthiest

Must meet all requirements of the original claim to make this statement

Schwan's and Nestle Warning Letters

Making 0 g trans fat claim

Had sodium or fat above the disclosure level

Did not have disclosure statement

Industry had believed this was a factual statement prior to warning letter

Many companies changed many labels after warning letter

Feb 2010

Light Warning Letter

Company has used light to describe color of product

FDA said if used to describe color

- Must include descriptive language

Companies have removed from labels

Feb 2010

Infant and Toddler Claims

Nutrient content claims are not permitted on foods for people less than 2 years of age

Allowed claims

- Statement of percent DV of vitamins and minerals
- Some comparative claims that are based in facts
- Unsweetened and unsalted are allowed if flavor (taste) claims

21CFR101.13

Infant Claim Warning Letter

Feb 2010

FDA letter stating nutrition claims not allowed on infant and toddler products

Claims have not been removed

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202834.htm

Health Claims

Health Claims

Any claim where a disease is referenced

Does not have to be a direct reference

Must be prior approved by FDA

- Done by petition to FDA
- Timing is between 120 days and years
- More details coming

Must use exact language FDA approved

- Can put claim in 2 locations
- CFR states model claim, industry uses only exact model language

Disqualification Levels

Disclosure levels change to disqualification for health claims

21CFR101.14

	Individual Foods	Main Dish	Meal
Fat	13	19.5 g	26 g
Sat Fat	4 g	6 g	8 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

Enforcement Discretion

When the FDA allows companies to do things that not defined by the regulation

Commonly done with nutrition claims

- Especially health claims

Types of Health Claims

Codified Health Claims (SSA)

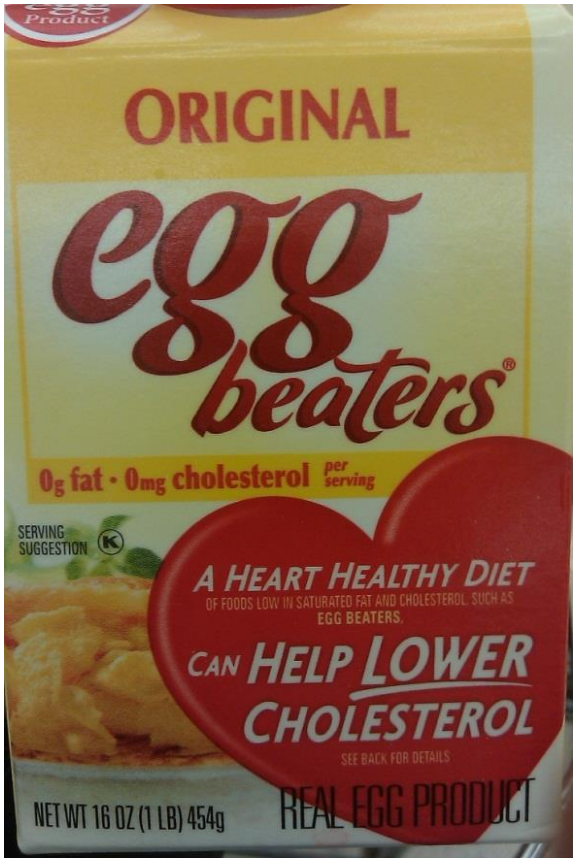
- 10 claims listed in CFR
- Require specific language

Qualified Health Claims

- Submitted and approved by FDA
- Require specific language
- Significant substantiation is required to get FDA approval

FDA approval takes times

No unapproved claims



SSA Claims

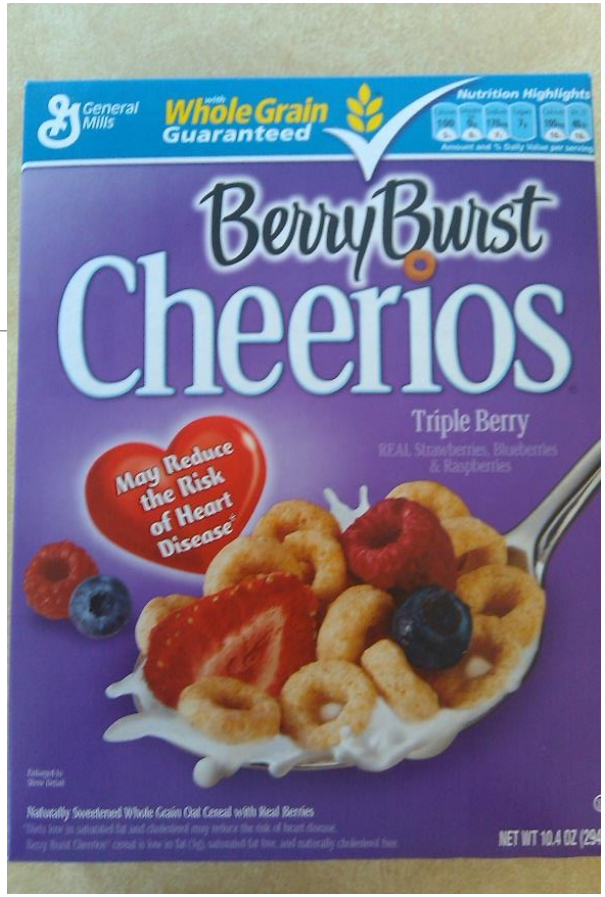
Significant Scientific Agreement

Defined in the CFR

- There are currently 10 defined claims

Approved through the FDA petition process

- Company files a petition
- FDA reviews data and publishes ANPR
- Comment period
- FDA issues final rule



Have not had any petitions or approved any claims since Qualified Claims where allowed

Requires a lot of data to submit petition

CFR includes justification for claim

Calcium, Vitamin D and Osteoporosis

Must be excellent source of calcium or calcium and vitamin D

Must not contain more phosphorus than calcium

Calcium and Osteoporosis model claims

- Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.
- Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

Calcium and Vitamin D and Osteoporosis model claims

- Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.
- Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

21CFR101.72

Dietary Lipids and Cancer

Food must be low fat

Model Claims

- Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
- Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking, and what you eat.

21CFR101.73

Sodium and Hypertension

Must be low sodium

Model Claims

- Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
- Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

21CFR101.74

Dietary Saturated Fat and Cholesterol and Coronary Heart Disease

Product must be

- Low fat
- Low sat Fat
- Low cholesterol
- Extra lean for fish and game meats

Model claims

- While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease
- Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles
- Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease
- Many factors, such as a family history of the disease, increased blood- and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes, and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol, and total fat may help reduce the risk of heart disease
- Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity

Fiber Containing Grain Products, Fruits, and Vegetables and Cancer

Product must be

- Grain product, fruit or vegetable
- Low fat
- Good source of fiber

Model Claims

- Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors
- Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits, and vegetables that contain dietary fiber may reduce your risk of some cancers

21CFR101.76

Fruits, Vegetables and Grain Products and Soluble Fiber and Coronary Heart

Product must be

- Grain product, fruit or vegetable
- Low fat
- Low sat fat
- Low cholesterol
- Must contain 0.6 g soluble fiber per RACC without fortification
  - Soluble fiber must be listed in nutrition facts panel

Model Claims

- Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
- Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

21CRF101.77

Fruits, Vegetables and Cancer

Product must be

- Fruit or vegetable
- Low fat
- Good source of Vitamin A, Vitamin C or Dietary Fiber without fortification

Model Claims

- Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.
- Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.

21CFR101.78

Folate and Neural Tube Defect

Product must be

- Good source of Folate
  - Folate must be included in the nutrition facts panel
  - May not contain more than 100% of the DV of folate

Model Claims

- Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.
- Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.
- Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

21CFR101.79

Dietary Non-cariogenic Carbohydrates and Dental Carries

Product must be

- Must contain xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, and erythritol, or a combination of these, D-tagatose, isomaltulose or sucralose
- Must meet sugar free with the exception of D-tagatose and isomaltulose

Model Claims

- Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.
- (Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.
- Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar used to sweeten this food, unlike other sugars, may reduce the risk of dental caries.
- Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar in [name of food], unlike other sugars, does not promote tooth decay.
- Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay.
- Example of the shortened claim for small packages:
  - Does not promote tooth decay.
  - May reduce the risk of tooth decay.

21CFR101.80

Soluble Fiber and Coronary Heart Disease

Product must be

- Must contain whole oats or barley foods
- Food containing oatrim or barley betafiber must have at least 0.75 g of beta-glucan soluble fiber
- Food containing phyllium must have at least 1.7 g of soluble fiber
- Soluble fiber must be declared in the nutrition facts panel
- Product must be low fat, low sat fat and low cholesterol

Model Claims

- Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of food product], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies _____ grams of the [grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] soluble fiber from [name of the soluble fiber source from paragraph (c)(2)(ii) of this section] necessary per day to have this effect.
- Diets low in saturated fat and cholesterol that include [_____grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] of soluble fiber per day from [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] may reduce the risk of heart disease. One serving of [name of food] provides ____ grams of this soluble fiber.

21CFR101.81

Soy Protein and Coronary Heart Disease

Product must be

- 6.25 g of soy protein per RACC
- Low fat, low sat fat and low cholesterol

Model Claims

- 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of food] supplies __ grams of soy protein.
- Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [name of food] provides __ grams of soy protein.

21CFR101.82

Plant Sterol/Stanol Esters and Coronary Heart Disease

Product must be

- 0.65 g of plant sterol or 1.75 g of stanol esters
- Low sat fat and low cholesterol
- Have less than disclosure for fat required for food type

Model Claims

- Foods containing at least 0.65 g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ___grams of vegetable oil sterol esters.
- Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 1.3 g of vegetable oil sterol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies ___grams of vegetable oil sterol esters.
- Foods containing at least 1.7 g per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies ___grams of plant stanol esters.
- Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 g of vegetable oil stanol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies ___grams of vegetable oil stanol esters.

21CFR101.83

Qualified Health Claims

Developed because SSA claims took so long to get approved

FDA reviews and defines enforcement discretion

Example:

- Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn 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 corn oil."

Process for Approval

Petition submitted

- Includes requested claims
- Science to support the claim

FDA reviews data provided and other data

FDA responds

- Letter of Denial
- Ask more questions
- Industry may withdraw request
- Letter of Enforcement Discretion
  - Includes requirements and language

Whey Protein Partially Hydrolyzed Infant Formula and Atopic Dermatitis

Model Claims

- "Very little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age."
- "Little scientific evidence suggests that, for healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life."
- "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life and up to 3 years of age. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is very little scientific evidence for the relationship."
- "For healthy infants who are not exclusively breastfed and who have a family history of allergy, feeding a 100% Whey-Protein Partially Hydrolyzed infant formula from birth up to 4 months of age instead of a formula containing intact cow's milk proteins may reduce the risk of developing atopic dermatitis throughout the 1st year of life. FDA has concluded that the relationship between 100% Whey-Protein Partially Hydrolyzed infant formulas and the reduced risk of atopic dermatitis is uncertain, because there is little scientific evidence for the relationship."
- "Partially hydrolyzed formulas **should not be fed to infants who are allergic to milk or to infants with existing milk allergy symptoms**. If you suspect your baby is already allergic to milk, or if your baby is on a special formula for the treatment of allergy, your baby's care and feeding choices should be under a doctor's supervision.

Selenium and Cancer

Model Claims

- Bladder Cancer
  - "One study suggests that selenium intake may reduce the risk of bladder cancer in women. However, one smaller study showed no reduction in risk. Based on these studies, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of bladder cancer in women."
- Prostate Cancer
  - "Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate cancer."
- Thyroid Cancer
  - "One weak, small study suggests that selenium intake may reduce the risk of thyroid cancer. Based on this study, FDA concludes that it is highly uncertain that selenium supplements reduce the risk of thyroid cancer."

Antioxidant Vitamin C and E and Cancer

Model Claims

- Vitamin C
  - Gastric (Stomach) Cancer
    "One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer."
- Vitamin E
  - Bladder Cancer
    - "One small study suggests that vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer."
  - Colorectal Cancer
    - "Two weak studies and one study with inconsistent results suggest that vitamin E supplements may reduce the risk of colorectal cancer. However, another limited study showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of colorectal cancer."
  - Renal Cell Cancer
    - "One weak and limited study suggests that vitamin E supplements may reduce the risk of renal cell cancer. FDA concludes that it is highly uncertain that vitamin E supplements reduce the risk of renal cell cancer."

Tomatoes and Cancer

Model Claims

- Prostate Cancer
  - "Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim.“
- Gastric Cancer
  - "Four studies did not show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer.“
- Ovarian Cancer
  - "One study suggests that consumption of tomato sauce two times per week may reduce the risk of ovarian cancer; while this same study shows that consumption of tomatoes or tomato juice had no effect on ovarian cancer risk. FDA concludes that it is highly uncertain that tomato sauce reduces the risk of ovarian cancer.“
- Pancreatic Cancer
  - "One study suggests that consuming tomatoes does not reduce the risk of pancreatic cancer, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer."

Tomatoes and Prostrate Cancer

Model Claims

- Prostate Cancer
  - "Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence supporting this claim."

Calcium and Colon/Rectal Cancer

Product must be

- 20% DV of calcium required

Model Claims

- "Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer, however, FDA has determined that this evidence is limited and not conclusive.“
- "Very limited and preliminary evidence suggests that calcium supplements may reduce the risk of colon/rectal polyps. FDA concludes that there is little scientific evidence to support this claim."

Green Tea and Cancer

Model Claims

- Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence for this claim.
- 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 and Cancer

Model Claims

- "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.“
- "Selenium may produce anticarcinogenic effects in the body. Some scientific evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive."

Antioxidant Vitamins and Cancer

Model Claims

- 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.
- Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive.
- FDA has determined that although some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.

B Vitamins and Vascular Disease

Model Claims

- As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease.*
- *FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and other vascular diseases, the evidence in support of the above claim is inconclusive.

Folic Acid, Vitamin B6 and Vitamin B12 and Vascular Disease

Model Claims

- It is known that diets low in saturated fat and cholesterol may reduce the risk of heart disease. The scientific evidence about whether folic acid, vitamin B6 and vitamin B12 may also reduce the risk of heart disease and other vascular diseases is suggestive, but not conclusive. Studies in the general population have generally found that these vitamins lower homocysteine, an amino acid found in the blood. It is not known whether elevated levels of homocysteine may cause vascular disease or whether high homocysteine levels are caused by other factors. Studies that will directly evaluate whether reducing homocysteine may also reduce the risk of vascular disease are not yet complete.

Walnuts and Coronary Heart Disease

See nutrition facts is required with claim

- Fat is over disqualification level

Enforcement discretion on 10% positive nutrient

- Close on protein and fiber

Model Claims

- 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.

Nuts and Coronary Heart Disease

See nutrition facts is required with claim

- Fat is over disqualification level

Enforcement discretion on 10% positive nutrient

- Close on protein and fiber

Model Claims

- "Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [, such as *name of specific nut*,] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.]"

Omega 3 and Coronary Heart Disease (Martek)

See nutrition facts is required with claim

- Fat, sat fat and cholesterol over disqualification level

Model Claims

- Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]

Omega 3 and Coronary Heart Disease (Wellness)

See nutrition facts is required with claim

- Fat, sat fat, cholesterol over disqualification level

Model Claims

- Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]

Corn Oil and Heart Disease

See nutrition facts is required with claim

- Fat is over disqualification level

Model Claims

- "Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn 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 corn oil."

Unsaturated Fat from Canola Oil and Coronary Heart Disease

See nutrition facts is required with claim

- Fat, sat fat and cholesterol over disqualification level

Model Claims

- "Limited and not conclusive scientific evidence suggests that eating about 1 ½ tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola 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 canola oil."

Monounsaturated Fat from Olive Oil and Coronary Heart Disease

See nutrition facts is required with claim

- Fat and sat fat over disqualification level

Model 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."

Phosphatidylserince and Cognitive Function

Model Claims

- "Very limited and preliminary scientific research suggests that PS may reduce the risk of dementia [cognitive dysfunction] in the elderly. FDA concludes that there is little scientific evidence supporting this claim."

Psyllium Husk and Type 2 Diabetes

Product must be

- No set level required

Model Claims

- "Psyllium husk may reduce the risk of type 2 diabetes, although the FDA has concluded that there is very little scientific evidence for this claim."
- "Psyllium husk may reduce the risk of type 2 diabetes. FDA has concluded that there is very little scientific evidence for this claim."

Whole Grains and Diabetes

Product must be

- 12 g whole grains required

Model Claims

- “Whole grains may reduce the risk of type 2 diabetes, although the FDA has concluded that there is very limited scientific evidence for this claim.”
- “Whole grains may reduce the risk of type 2 diabetes. FDA has concluded that there is very limited scientific evidence for this claim.”

Chromium Picolinate and Type 2 Diabetes

Product must be

- 20% DV is required

Model Claims

- "One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."

Calcium and Hypertension

20% DV of calcium required per serving

Model Claims

- Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that the evidence is inconsistent and not conclusive.
- Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced hypertension.
- Three studies, including a large clinical trial, do not show that calcium supplements reduce the risk of preeclampsia during pregnancy. However, two other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of preeclampsia.

Folic Acid and Neural Tube Defects

Product must be

- Good source of Folic acid
- Must list folic acid in the nutrition facts panel.

Model Claims

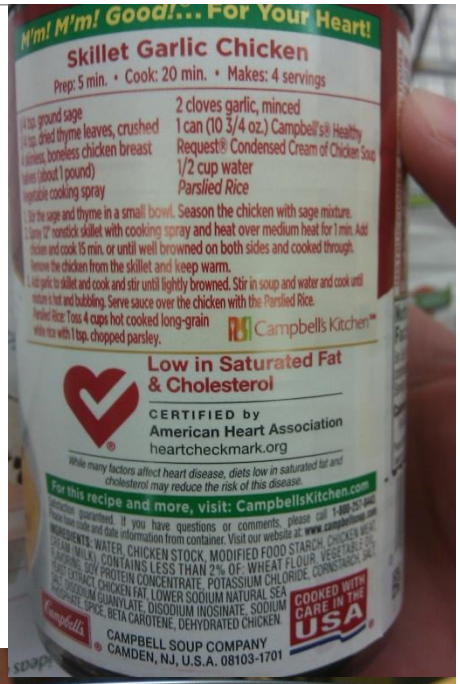
- Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The Institute of Medicine of the National Academy of Sciences recommends that women capable of becoming pregnant consume 400 mcg folate daily from supplements, fortified foods, or both, in addition to consuming food folate from a varied diet.
- Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. The scientific evidence that 400 mcg folic acid daily reduces the risk of such defects is stronger than the evidence for the effectiveness of lower amounts. This is because most such tests have not looked at amounts less than 400 mcg folic acid daily.
- Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. Women capable of becoming pregnant should take 400 mcg folate/day from fortified foods and/or a supplement, in addition to food folate from a varied diet. It is not known whether the same level of protection can be achieved by using only food that is naturally rich in folate. Neither is it known whether lower intakes would be protective or whether there is a threshold below which no protection occurs.
- Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect. Women capable of becoming pregnant should take 400 mcg of folate per day from a supplement or fortified foods and consume food folate from a varied diet. It is not known whether the same level of protection can be achieved by using lower amounts.

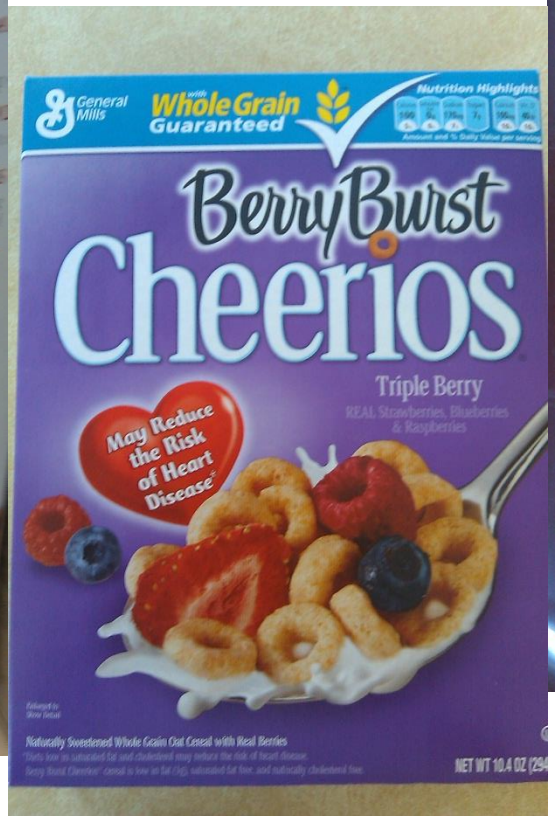
American Heart Association

AHA has a heart check program

- Total Fat: Less than 6.5 g
- Saturated Fat: 1 g or less and 15% or less calories from saturated fat
- Trans Fat: Less than 0.5 g (and label serving)
- Cholesterol: 20 mg or less
- Sodium: 480 mg or less (also per label serving)
- Beneficial Nutrients: 10% or more of the Daily Value of 1 of 6 nutrients (vitamin A, vitamin C, iron, calcium, protein or dietary fiber)
- Other requirements for specific foods

Considered a health claim by FDA





Hearts are considered a health claim

Must use a defined claim

Structure Function Claims

Claims that talk about the function of a nutrient

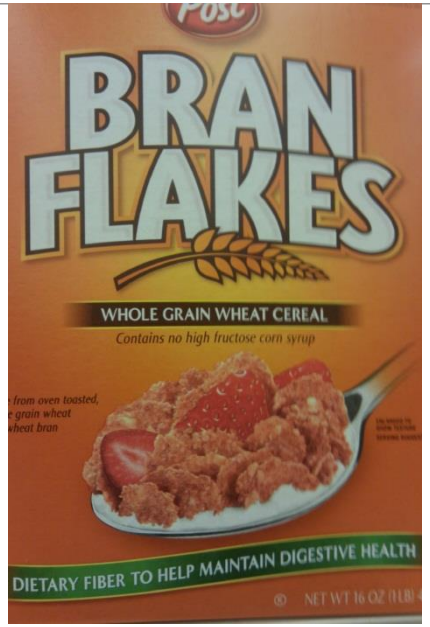
May not include a disease reference

Must have a good or excellent source of the nutrient

Must have significant scientific agreement for the claim

Example:

- Protein helps build strong bones



Nutrition Claims

Dual column products (200 – 400% RACC)

Claim statement must be added

Nutrient Content Claim

- A serving of ___ ounces of this product contains ___ mg of calcium

Health Claim

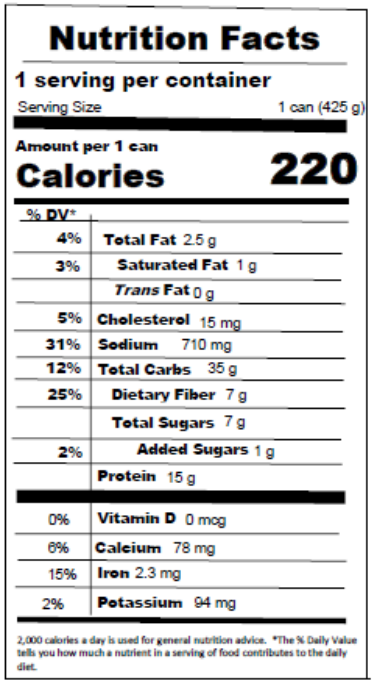
- A serving of ___ ounces of this product conforms to such diet.

Disclosure still required as needed

Example
Healthy Choice Soup

CURRENT NF PANEL

PROPOSED NF PANEL



What Next?

New claims?

Changes because of nutrition labeling changes

Industry would like to have claims changes at same time as nutrition labeling changes

FDA has said that is not going to happen

FDA left open for claim changes in future