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## *Food Labeling: Foods and Dietary Supplements*

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### Overview

#### Definition of Food Labeling

Food labeling consists of the information present on all food packages. Nutrition labeling is one component of the food label. Other components include the principal display panel, the information panel, the identity of the food, the list of ingredients, the name and place of business of the manufacturer, packer, or distributor, as well as any claims made.<sup>1</sup>

#### Progression of the Section

This section reviews the regulatory history of food labeling, the required portions of the nutrition label, labeling of restaurant and fresh foods, definitions of allowed nutrient content claims, and requirements for allowed health claims and structure/function claims. Additional resources for food labeling are provided.

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### History of Food Labeling

#### Major Food and Nutrition Labeling Laws and Regulations

Food labeling laws progressed from protecting consumers from economic harm (Pure Food and Drug Act of 1906)<sup>2</sup> to reducing consumers' risk of chronic disease (Nutrition Labeling and Education Act of 1990<sup>3</sup> [NLEA]). The NLEA amended the Food, Drug, and Cosmetic Act of 1938<sup>4</sup> and required that nutrition information be conveyed to consumers so they could readily understand the information and its significance in the context of a total daily diet. The NLEA<sup>3</sup> mandated major revisions in the Food and Drug Administration's (FDA) food labeling regulations, including requiring nutrition labeling on almost all processed foods, a revised list of nutrients to be labeled, standardized serving sizes,

**TABLE 14.1****Major Food and Nutrition Labeling Laws/Selected Regulations**

<b>Law</b>	<b>Primary Provisions</b>
Pure Food and Drug Act, 1906 <sup>2</sup>	Barred false and misleading statements on food and drug labels.
Federal Food, Drug, and Cosmetic Act, 1938	Replaced the Pure Food and Drug Act of 1906. Created distinct food labeling requirements. Required “common and usual name” of food, ingredient declarations, net quantity information, name and address of manufacturer/distributor. Defined misbranding. <sup>4</sup>
Fair Packaging and Labeling Act, 1966	Provided FDA with authority to regulate provision of label information and package size. <sup>8</sup>
Regulations for enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act	Merged existing regulations into one entity. Required nutrition labeling on processed foods that were fortified or carried claims. Provided for labeling of fat and cholesterol. Established standards for dietary supplements. Established regulations for artificially flavored foods and imitation foods per serving. Disallowed nutrient claims unless food contained 10% or more of the US RDA. Incorporated label information: number of servings/container; calories, protein, carbohydrate, and fat content; percentage of adult US RDA for protein and seven vitamins and minerals. Provided for sodium labeling without requirement for the full nutrition label panel. <sup>9-11</sup>
Nutrition Labeling and Education Act, 1990	Provided for mandatory nutrition labeling on almost all food products, expanded required nutrition information in a new format, created standardized serving sizes, provided consistent definitions of nutrient content claims, and defined permissible health claims. <sup>3</sup>
Dietary Supplement Health and Education Act, 1994	Defined dietary supplements, provided for nutrition labeling in a new format, required the name and quantity of every active ingredient, provided for structure/functions claims and good manufacturing practices, encouraged research on dietary supplements, created two new government entities: Commission on Dietary Supplement Labels and the Office of Dietary Supplements. <sup>12</sup>
FDA Modernization Act, 1997	Expanded procedures by which FDA can authorize health claims and nutrient content claims, e.g., provided for a notification process. <sup>13</sup>

nutrient content claims, and for the first time, health claims. In the interest of harmony and uniformity, the U.S. Department of Agriculture’s Food Safety and Information Service (FSIS) issued similar regulations for meat and poultry products.<sup>5</sup> Table 14.1 summarizes the major laws and selected regulations dealing with food labeling. (For further details, see Geiger, 1992<sup>6</sup> and Geiger, 1998.<sup>7</sup>)

### Regulatory Oversight for Labeling

A number of regulatory agencies have jurisdiction over food labeling, including FDA, USDA, Federal Trade Commission (FTC), and Bureau of Alcohol, Tobacco and Firearms (BATF). Table 14.2 shows their responsibilities.

**TABLE 14.2**

## Agencies having Jurisdiction over Food Labeling

Agency	Responsibility
FDA	Mandatory labeling of most packaged foods except products containing certain amounts of meat and poultry, and beverages with certain amounts of alcohol. Voluntary labeling of fresh fruits and vegetables, fresh fish, game, and restaurant foods except those containing certain amounts of meat and poultry
USDA	Mandatory labeling on most processed meat and poultry products, e.g., hot dogs, chicken noodle soup
FTC	Claims made in food advertising
BATF	Voluntary labeling of alcoholic beverages

## Required Portions of the Food Label

Required sections of the Nutrition Facts Label (see Figure 14.1) are illustrated here. The nutrition facts information is based on a serving of the product as packaged.

### Required Nutrients

The nutrients required to be labeled in the Nutrition Facts Panel are listed in [Table 14.3](#). If a product is fortified with a certain nutrient or a claim is made about a voluntary nutrient, then that nutrient also is required to be labeled. Other nutrients (voluntary nutrients) that may be included on the label are found in [Table 14.3](#).

### Serving Size

Standardized serving sizes, known as Reference Amounts Customarily Consumed (RACCs), are established for many categories of foods. RACCs are based on average amounts people usually eat at one time, based on USDA survey data. These uniform serving sizes help consumers compare products. See [Table 14.4](#) for selected RACCs.

### Kcalories and Kcalories from Fat

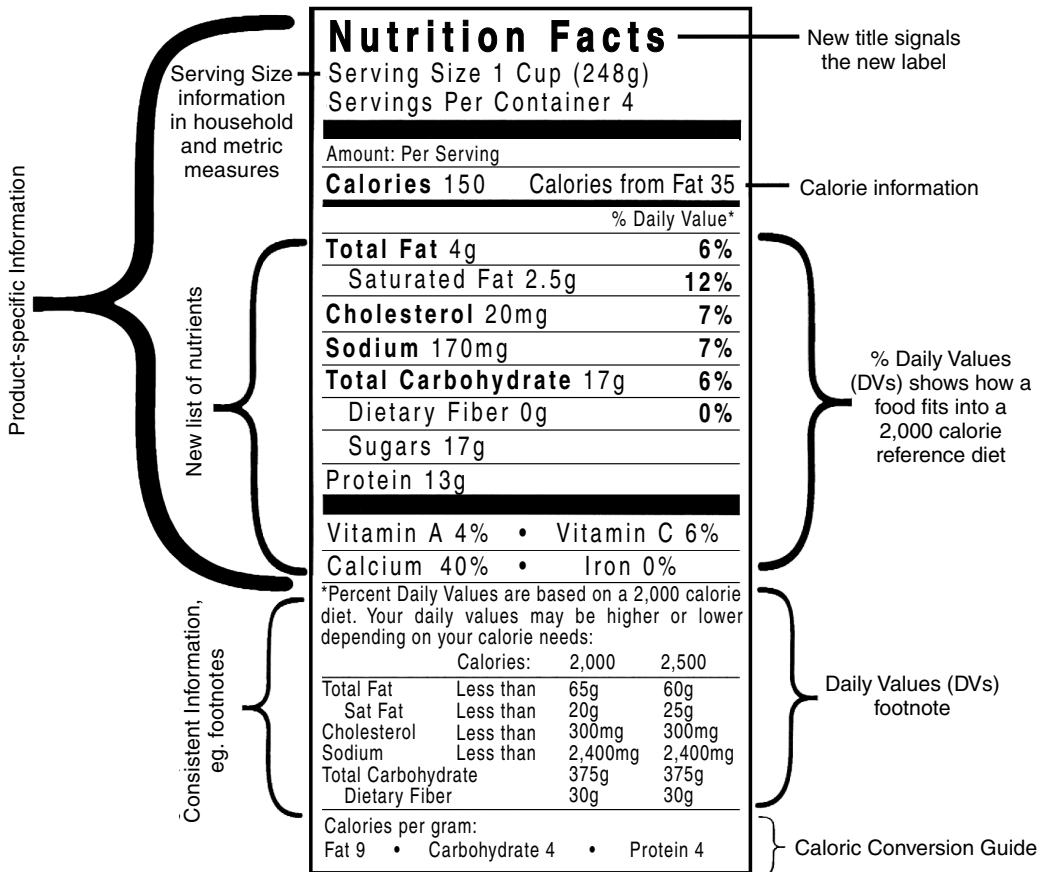
Amount of kcalories and kcalories from fat are required because of public health authorities' concerns with fat in the diet.

### Daily Values

The standards for labeling of nutrients are known as Daily Values (DVs). The percent of DV is listed for certain nutrients on the label so that consumers can determine how a serving of a food fits into their total daily diet. The DVs include Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs). DRVs are set for nutrients that previously did not have label standards, such as fat, cholesterol, and saturated fat (see [Table 14.5](#)). DRVs are based on a daily intake of 2000 kcalories, which is a reasonable reference number for adults and children over four, and are calculated based on current nutrition recommendations. The

# THE NEW LABEL FORMAT

## Product: Plain Yogurt



THIS LABEL IS ONLY A SAMPLE. EXACT SPECIFICATIONS ARE IN THE CODE OF FEDERAL REGULATIONS.



AMERICAN DIETETIC ASSOCIATION

FIGURE 14.1

Nutrition facts panel (© 1994, American Dietetic Association. *Learning the New Food Labels*. Used with permission).

**TABLE 14.3**Labeling of Nutrients: Required and Voluntary<sup>1</sup>

Required Nutrients	Voluntary Nutrients
Total kcalories	kcalories from saturated fat
kcalories from fat	kcalories from polyunsaturated fat
Total fat	kcalories from monounsaturated fat
Saturated fat	Potassium
Cholesterol	Soluble fiber
Sodium	Insoluble fiber
Total carbohydrate	Sugar alcohol
Dietary fiber	Other carbohydrates
Sugars	Other essential vitamins and minerals
Protein	
Vitamin A	
Vitamin C	
Calcium	
Iron	

**TABLE 14.4**Selected Reference Amounts Customarily Consumed (RACCs)<sup>1,a</sup>

Category	RACC
Bakery products: biscuits, bagels, tortillas, soft pretzels	55 g
Beverages: carbonated and noncarbonated beverages, wine coolers, water; coffee or tea, flavored and sweetened; juice, fruit drinks	240 mL
Breads	50 g
Cereals and other grain products	Varies from 25 g for dry pasta to 140 g for prepared rice
Cheese	30 g
Eggs	50 g
Fats and oils	1 tbsp
Fruits: fresh, canned, or frozen except watermelon	140 g
Meat: entrees without sauce	85 g cooked; 110 g uncooked
Nuts and seeds	30 g
Soups	245 g
Vegetables; fresh, canned, or frozen	85 g fresh or frozen 95 g for vacuum packed 130 g for canned in liquid

<sup>a</sup> See 21 CFR 101.12 for details.**TABLE 14.5**DRVs for Adults: Calculations and Values<sup>1</sup>

Nutrient	Derivation/Calculation	Label Value
Fat	30% of 2000 kcalories from fat = 600 kcalories/9 kcalories/g	65 g
Saturated fat	10% of kcalories from saturated fat = 200 kcalories/9 kcalories/g	20 g
Carbohydrate	60% of kcalories from carbohydrate = 1200 kcalories/ 4 kcalories/g	300 g
Protein	10% of kcalories from protein = 200 kcalories/ 4 kcalories/g	50 g
Fiber	11.5 g per 1000 kcalories	25 g (rounded up)
Cholesterol	NA	<300 mg
Sodium	NA	<2400 mg
Potassium	NA	3500 mg

**TABLE 14.6**RDIs for Adults and Children over 4<sup>1</sup>

Nutrient	RDI
Vitamin A	5000 IU
Vitamin C	60 mg
Calcium	1000 mg
Iron	18 mg
Vitamin D	400 IU
Vitamin E	30 IU
Vitamin K	80 µg
Thiamin	1.5 mg
Riboflavin	1.7 mg
Niacin	20 mg
Vitamin B <sub>6</sub>	2.0 mg
Folate	400 µg
Vitamin B <sub>12</sub>	6 µg
Biotin	300 µg
Pantothenic acid	10 mg
Phosphorus	1000 mg
Iodine	150 µg
Magnesium	400 µg
Zinc	15 mg
Selenium	70 µg
Copper	2 mg
Manganese	2 mg
Chromium	120 µg
Molybdenum	75 µg
Chloride	2400 mg

term RDIs replaces the term U.S. Recommended Dietary Allowances (RDAs), but the values are currently the same as the U.S. RDAs, which represent the highest recommended levels of the 1968 RDAs (see Table 14.6). The RDI values will be updated when the National Academy of Sciences completes its latest review of all nutrient recommendations.

A DVs footnote is provided at the bottom of the label to inform consumers of the DVs for both 2000- and 2500-calorie levels. The calorie information at the bottom of the label is voluntary (see Figure 14.1).

### Substances without DVs

Substances without DVs, such as sugars and soluble and insoluble fiber, are not required to carry a percent of DV. For dietary supplement labels, substances such as herbs are separated from the nutrients. The amount of the herb must be listed along with a symbol referring to the statement “Daily Value not established.”

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## Labeling of Restaurant Foods and Fresh Foods

### Restaurant Foods

Labeling of restaurant foods is voluntary. If a nutrient content claim or health claim is made, then nutrition labeling becomes mandatory. However, the full Nutrition Facts Label

does not need to appear. Only the amount of the nutrient that is the subject of the claim needs to be labeled, e.g., “low fat,” contains 3 g of fat.

### **Fresh Fruits, Vegetables, and Seafood**

The FDA recommends that food retailers provide nutrition information for raw fruits, vegetables, and fish at point of purchase. Charts, brochures, or signs can be used to depict nutrition information for the 20 most commonly consumed fruits, vegetables, and raw fish. The FDA provides the data for retailers in the *Code of Federal Regulations* (21 CFR 101.45 and Appendix C to Part 101).

### **Meats and Poultry**

The USDA recommends that food retailers provide point-of-purchase information for meat and poultry. As with fresh produce and fish, charts, brochures, or signs can be used to depict the nutrition information.<sup>5</sup>

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## **Nutrient Content Claims Allowed for Foods and Dietary Supplements**

### **Overview**

The FDA and USDA have issued regulations for uniform definitions for nutrient content claims. A nutrient content claim characterizes the level of a nutrient in a food, e.g., “high fiber.” Two types of nutrient content claims can be made: absolute (free, low, good source, high, lean, extra lean) and comparative (reduced, light, less, more). The regulations establish the allowed terms and the criteria/requirements for their use (see [Tables 14.7, 14.8](#)).<sup>1</sup> For additional detail see the *Code of Federal Regulations* (21 CFR 101.13 and 101.54-101.69).

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## **Health Claims Allowed for Foods and Dietary Supplements**

### **Overview**

NLEA allowed health claims to be carried on qualified food products. Prior to this time, these claims were considered unauthorized drug claims. A health claim describes the relationship between a food, a nutrient, or other substance in a food, and the risk of a health-related condition or disease.

Health claims can be made through third-party references, such as the American Heart Association, symbols such as a heart, statements, and vignettes or descriptions. Regardless of the manner of presentation, the requirements for the claim must be met in order for a food or supplement to carry the claim on its product packaging or in its advertising. Health claims carry general and specific requirements. General requirements include not exceeding certain amounts of fat (13 g), saturated fat (1 g), cholesterol (40 mg), and sodium (480 mg). The food must be a “good source” of fiber, protein, vitamin A, vitamin C, calcium, or iron. The specific requirements for each health claim are listed in the *Code of Federal*

**TABLE 14.7**Allowed Nutrient Content Claims with Definitions<sup>1, a, b</sup>

Claim	Calories	Fat	Saturated Fat	Cholesterol	Sodium	Fiber	Sugar	Protein	Vitamins/ Minerals
“Free,” “no,” “zero,” “without”	Less than 5 kcalories	0.5 g or less	0.5 g or less	Less than 2 mg cholesterol and 2 g or less saturated fat and trans fat	Less than 5 mg	NA	Less than 0.5 g	NA	NA
“Very low”	NA	NA	NA	NA	Less than 35 mg	NA	NA	NA	NA
“Low,” “contains a small amount,” “little”	40 kcalories or less	3 g or less	1 g or less	20 mg or less cholesterol and 2 g or less saturated fat	140 mg or less	NA	NA	NA	NA
“Reduced”	25% lower in kcalories than the comparable food	25% lower in kcalories than the comparable food	25% lower in kcalories than the comparable food	25% lower in kcalories than the comparable food	25% lower in kcalories than the comparable food	NA	25% lower in kcalories than the comparable food	NA	NA
“Light”	1/3 fewer kcalories than the reference foods, only if the reference food contains less than 50% calories from fat	50% less fat than the reference food	NA	NA	50% less sodium than the reference food, food also is low fat and low calorie	NA	NA	NA	NA
“Good source,” “provides,” “contains”	NA	NA	NA	NA	NA	2.5-4.9 g	NA	5 g or more	10 — 19% of the DV
“High,” “excellent source of,” “rich in”	NA	NA	NA	NA	NA	5 g or more	NA	10 g or more	20% or more of the DV
“More,” “added,” “enriched,” “fortified”	NA	NA	NA	NA	NA	NA	NA	10% more of the DV (5 g)	10% more of the DV

<sup>a</sup> Definitions vary for meal and main dishes.<sup>b</sup> Complete definitions are found in 21 CFR 101.13 and 21 CFR 101.54-101.69.



**TABLE 14.8**Other Nutrient Content Claims Definitions<sup>a,b</sup>

Claim	Definition
% Fat-free	Must be "low-fat" or "fat-free." Must indicate the amount of fat present in 100 g of food
Lean	Less than 10 g fat, less than 4 g saturated fat, less than 95 mg cholesterol per RACC and per 100 g
Extra lean	Less than 5 g fat, less than 2 g saturated fat, less than 95 mg cholesterol per RACC and per 100 g

<sup>a</sup> Definitions vary for main dish and meal products.<sup>b</sup> Complete definitions are found in 21 CFR 101.13 and 21 CFR 101.54-101.69.

*Regulations* (21 CFR 101.14; 101.70-101.81), except for those authorized through FDAMA or by the courts.

Current health claims are authorized in three ways: by FDA as a result of NLEA, which also allowed for petitions for new health claims (12 claims); by notification of FDA through FDAMA (two claims); or through court action as a result of the *Pearson* decision (two claims at time of section submission). FDAMA allowed FDA to authorize a health claim if a scientific body of the U.S. Government that has official responsibility for human nutrition research or public health protection publishes a current authoritative statement. A company or organization must notify FDA at least 120 days prior to the introduction of the food carrying the claim into interstate commerce. FDAMA health claims, unlike the other claims, do not allow an opportunity for public comment. If FDA takes no action within 120 days of the notification, the health claim can be made on the food qualifying for the claim. The *Pearson* decision resulted from a lawsuit filed by Durk Pearson, Sandy Shaw, and the American Preventive Medical Association to allow four previously denied health claims to be made on dietary supplements. The court decision mandated that FDA 1) reconsider whether to authorize the four previously denied health claims, 2) determine if the weight of the scientific evidence in support of the claim is greater than that against it, and 3) if so, then determine if qualifying language would not mislead consumers. FDA is also required to define significant scientific agreement.

FDA authorized seven claims as a result of NLEA. Since that time, FDA has approved an additional three claims submitted as petitions, two claims submitted as notifications through FDAMA, and two claims as a result of the *Pearson* decision.

The health claim model language and requirements are indicated in three tables: those resulting from NLEA and petitions (Table 14.9); those not prohibited by FDA through FDAMA (Table 14.10), and those allowed by court decision that carry extensive qualifying language (Table 14.11). Again, the requirements for the FDAMA and court-mandated (*Pearson* decision) health claims do not appear in the *Code of Federal Regulations*.

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## Structure Function Claims

### Overview

Structure/function claims can be made on dietary supplements (DSHEA 1994).<sup>12</sup> A structure/function claim is characterized as a statement that describes the role of a nutrient or dietary ingredient that affects a function or structure of the body, or such claims can describe how such a substance maintains a structure or function.

**TABLE 14.9**Health Claims Authorized through the Regulations Implementing NLEA<sup>1,7</sup>

Health Claim	Model Language	Requirements	Can Be Made On Qualified
<i>Cancer</i>			
Fruits and vegetables and cancer	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 is a good source of dietary fiber	Food product must be or must contain a fruit or vegetable; product is "low fat;" product is a "good source" of at least one of the following: vitamin A, vitamin C, or fiber	Foods
Fiber-containing grain products, fruits and vegetables and cancer	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 risk factors	Food product must be or must contain a grain product, fruit, or vegetable; food product is "low fat," and is (prior to fortification) a "good source of dietary fiber"	Foods
Fat and cancer	Development of cancer depends on many factors. A diet low in total fat may reduce the risk for some cancers	Food product is "low fat;" fish and game meats must be "extra lean"	Foods
<i>Coronary Heart Disease</i>			
Fruits, vegetables and grain products that contain fiber, especially soluble fiber, and risk of coronary heart disease	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 risk of heart disease	Food products contains $\geq 0.6$ g soluble fiber; soluble fiber is listed on Nutrition Facts Panel. Food product must be "low fat," "low saturated fat," and "low cholesterol;" food is, or must contain, a vegetable, fruit, or grain product	Foods
Soluble fiber from certain foods (oats and psyllium) and coronary heart disease	Diets low in saturated fat and cholesterol that include ___ g of soluble fiber per day from (name of food) may reduce the risk of heart disease. One serving of (name of food) supplies ___ g of the ___ g necessary per day to have this effect	Food is "low saturated fat," "low cholesterol," and "low fat;" food contains $\beta$ -glucan soluble fiber from whole oats; food contains $\geq 0.75$ g whole oat soluble fiber; soluble fiber is listed on the Nutrition Facts Panel; or Food is "low saturated fat," "low cholesterol," and "low fat"; food contains $\geq 1.7$ g soluble fiber from psyllium husk; soluble fiber is listed on the Nutrition Facts Panel	Foods
Soy protein and coronary heart disease	Diets low in fat and cholesterol that include 25 g of soy protein a day may reduce the risk of heart disease. One serving of (name of food) provides ___ g of soy protein	Food contains $\geq 6.25$ g soy protein; food is "low cholesterol," "low saturated fat;" food is "low fat," unless it is derived from or consists of whole soybeans and contains no fat in addition to the fat naturally present in the whole soybeans it contains or from which it is produced	Foods

Saturated fat and cholesterol and coronary heart 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	Food must be “low saturated fat,” “low fat,” and “low cholesterol;” fish and game meats must be “extra lean”	Foods
Plant sterols/stanol esters and coronary heart disease	For 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 food] supplies ___ g of vegetable oil stanol esters For plant sterol esters: 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 food] supplies ___ g of vegetable oil sterol esters	Food contains 1.7 g of plant stanol esters/RACC (spreads, salad dressings, snack bars, and dietary supplements in softgel form) or 0.65 g of plant sterol esters/RACC (spreads and salad dressings); food is “low cholesterol” and “low saturated fat;” food must not exceed the fat disqualifying levels (13 g) of health claims unless it is a spread or a salad dressing. Those products (spreads or salad dressings) exceeding 13 g of fat must carry a disclosure statement referring people to the Nutrition Facts Panel for information about fat content; food contains 10% or more of the DV for vitamin A, vitamin C, iron, calcium, protein, or fiber unless the product is a salad dressing <sup>14</sup>	Foods and dietary supplements
<i>Other Health Claims</i>			
Calcium and osteoporosis	Regular exercise and a healthy diet with enough calcium help teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intakes are important, but daily intakes above 2000 mg are not likely to provide any additional benefit	Food or dietary supplement must be “high” in calcium	Foods and dietary supplements
Sodium and hypertension	Diets low in sodium may reduce the risk of high blood pressure, a disease caused by many factors	Food must be “low sodium”	Foods
Sugar alcohols and dental caries	Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol used to sweeten this food may reduce dental caries	Food must contain less than 0.5 g sugar; sugar alcohol in the food shall be sorbitol, isomalt, xylitol, lactitol, hydrogenated glucose syrup, hydrogenated starch hydrolysates, or a combination	Foods
Folic acid and neural tube defects	Healthful diets with adequate folate may reduce a woman’s risk of having a child with a brain or spinal cord defect	Food or supplements must be a “good source” of folate; claim cannot be made on foods that contain more than 100% of the RDI for vitamin A, such as preformed vitamin A or retinol, or vitamin D	Foods and dietary supplements

**TABLE 14.10**

## Health Claims Allowed to Pass Through FDAMA

Health Claim	Model Language	Requirements	Can Be Made on Qualified
Whole grains and CHD	Diets rich in whole grains and other plant foods and low in total fat, saturated fat, and cholesterol may help reduce the risk of heart disease and certain cancers	Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may help reduce the risk of heart disease and certain cancers <sup>15</sup>	Foods
Potassium-containing foods and blood pressure and stroke	Diets containing foods that are good sources of potassium and low in sodium may reduce the risk of high blood pressure and stroke	Foods contain at least 10% DV for potassium/RACC; food is "low sodium," "low cholesterol," "low saturated fat"/RACC; potassium is listed on the Nutrition Facts Panel <sup>16</sup>	Foods

**TABLE 14.11**

## Qualified Health Claims Allowed by the Pearson Decision

Health Claim	Model Language	Requirements	Can Be Made on Qualified
Omega-3 fatty acids and CHD	The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and not omega-3 fatty acids, and it is not known whether diets or omega-3 fatty acids in fish may have a possible effect on a reduced risk of coronary heart disease. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population	Dietary supplement cannot state the daily dietary intake necessary to achieve a claimed effect because the evidence is not definitive; labeling cannot recommend or suggest intakes of more than 2 g per day, preferable 1 g or less <sup>17</sup>	Dietary supplements
Folic acid, vitamin B <sub>6</sub> , vitamin B <sub>12</sub> and vascular disease	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 B <sub>6</sub> , and vitamin B <sub>12</sub> may also reduce the risk of heart disease and other vascular disease 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	Dietary supplement cannot state the daily dietary intake necessary to achieve a claimed effect because the evidence is not definitive; products with more than 100% DV (400 µg) of folic acid must identify the safe upper limit of 1000 µg in parentheses <sup>18</sup>	Dietary supplements

## Requirements

The general requirements for structure/function claims are: 1) the statement must be truthful and not misleading, 2) the manufacturer of the product carrying the claim must notify the FDA within 30 days of first marketing a dietary supplement, and 3) the dietary supplement must carry the following disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."<sup>12</sup>

Specific requirements for structure/function claims are not found in the *Code of Federal Regulations*. FDA does not approve individual claims.

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## Resources

### Food and Drug Association [www.fda.gov](http://www.fda.gov)

The FDA website provides a wealth of information about FDA regulatory actions and positions, industry guidance, and consumer education materials. The site provides FDA organizational structure and a telephone and email directory so that staff contacts can be made. The "What's New" section lists FDA's latest actions. A separate page is devoted to dietary supplements. Links are provided to other regulatory agencies such as the FTC and the FSIS.

### Food Safety and Inspection Service [www.fsis.gov](http://www.fsis.gov)

The USDA's FSIS is responsible for overseeing labeling of meat and poultry foods. The agency allows health claims on a case-by-case basis. (USDA requires label approval prior to use on a product.) FSIS's website provides regulatory guidelines and current information.

### *Code of Federal Regulations (CFR)* [www.access.gpo/nara/cfr/index.html](http://www.access.gpo/nara/cfr/index.html)

The CFR codifies all of the general and permanent rules published in the *Federal Register* by FDA and FSIS, USDA, FTC, and BATF. The CFR is divided into 50 titles, each representing an area of federal regulation, e.g., 21 CFR is Food and Drugs and 9 CFR is USDA. The titles are then divided into chapters that usually bear the name of the responsible agency. Those most pertinent to the food label include 21 CFR 100-169 (FDA, food labeling), 21 CFR 170-199 (FDA, food additives), and 9 CFR 200 to end (FSIS, food labeling). The CFR can be accessed online through the FDA website. The CFR is updated once per year.

### *Federal Register*

The *Federal Register* is one of the most important sources for information on any government agency's activities. Federal government agencies, such as FDA and USDA, publish regulations in the *Federal Register* to implement food and dietary supplement laws in various forms (notice, proposed rule, final rule) on a daily (Monday through Friday) basis. Once a final rule is published it becomes incorporated into the CFR. The *Federal Register* can be accessed through FDA's website. It can be searched by agency, date, date range, or topic.

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