

QUICK-REFERENCE GUIDE

Nutrition Claims for Dairy Products



Nutrition Facts	
Amount per serving	
Total Fat	8g
Total Cholesterol	25mg
Total Sodium	120mg
Total Carbohydrate	28g
Total Protein	8g
Total Sugar	12g
Total Fiber	3g
Total Fat	8g
Total Cholesterol	25mg
Total Sodium	120mg
Total Carbohydrate	28g
Total Protein	8g
Total Sugar	12g
Total Fiber	3g
Total Fat	8g
Total Cholesterol	25mg
Total Sodium	120mg
Total Carbohydrate	28g
Total Protein	8g
Total Sugar	12g
Total Fiber	3g



©2011 Dairy Research Institute™

The information in this guide is current as of November 2010. It is only intended to be a general summary of information, and is not intended to take the place of either the written law or regulations. For an authoritative source, the FDA Regulations are published in the CFR – Code of Federal Regulations, and are available online and in book format from the Superintendent of Documents, U.S. Government Printing Office. This summary does not constitute legal advice. You should consult with competent counsel to determine applicable legal requirements in a specific fact situation.

QUICK-REFERENCE GUIDE TO NUTRITION CLAIMS FOR DAIRY PRODUCTS

This *Quick-Reference Guide* made available by the Dairy Research Institute™ provides a basic understanding of nutrition claims and labeling rules, specifically, nutrition and health-related claims that represent potential opportunities for use with fluid milk, cheese and yogurt products.

Milk and other dairy foods are nutrient-rich and contribute substantial amounts of many nutrients to the U.S. diet, including calcium, potassium, phosphorus, magnesium, zinc, protein, vitamins A, D and B₁₂, and riboflavin. Many nutrition and health-related claims can be made, providing a valuable marketing tool for establishing a competitive advantage. This guide reviews key nutrition labeling terms associated with claims, discusses the categories of claims and serves as an overview of the regulations for the types of claims manufacturers can choose for select dairy products.

Increasingly, nutrition-conscious consumers are looking for health and wellness attributes when buying food. Unless they've done lots of research before going to the store, they rely on food labels and nutrition claims about the benefits of dairy foods to help guide their choices. Therefore, labeling and marketing claims can provide an important opportunity to showcase the nutrition and health benefits of dairy products. The Innovation Center for U.S. Dairy™ provides insights and resources to support the industry in this area; and for more information see <http://www.usdairy.com>.

It is important to remember that compliance with regulatory requirements and industry standards set forth by the U.S. Food and Drug Administration (FDA), the Federal Trade Commission (FTC) and other governing agencies is critical. ***This reference guide is not a comprehensive guide to FDA regulations covering size and placement of claims, and should not be considered as such.*** (More complete information on FDA regulations can be found in the Code of Federal Regulations, 21 CFR 101.) All health related claims must be substantiated and in compliance with regulations before being used in labeling or advertising. As regulations are subject to change over time, it is imperative that the most current regulations be consulted prior to making any claims.

About the Dairy Research Institute

The Dairy Research Institute™ is a 501(c)(3)* nonprofit organization affiliated with the Innovation Center for U.S. Dairy™. It was established in 2010 under the leadership of America's dairy farmers through Dairy Management Inc.™ (DMI), the nonprofit organization that manages the producer checkoff program. The Institute was created to strengthen the dairy industry's access to and investment in the technical research required to drive innovation and demand for dairy products and ingredients domestically and abroad. The Dairy Research Institute works with and through industry, academic, government and commercial partners to increase pre-competitive technical research in nutrition, products and sustainability on behalf of the Innovation Center and the National Dairy Council®.

*application pending

Table of Contents

REGULATORY OVERSIGHT 2

NUTRITION CLAIM BASICS

Overview of Nutrition Claims	3
■ Nutrient Content Claims	3
■ Health Claims	3
■ Structure/Function Claims	4
■ 'Reference Amount Customarily Consumed' and 'Label Serving Size'	4
■ 'Disclosure Statements' and 'Disqualifying Levels'	5
■ Daily Values Used on the Nutrition Facts Panel	5

Nutrient Content Claims

Overview/Definitions	7
Examples of Claims for Select Dairy Products (Charts)	11
■ 'High' and 'Good Source'	11
■ Fat and Saturated Fat	13
■ Cholesterol	15
■ Sodium	16
■ Sugar	17
■ Calorie	18
■ 'Light' or 'Lite'	19
■ Healthy	20
■ Numeric Declaration	20

Health Claims

Overview/Definitions	21
General Requirements for Health Claims	22
Potential Health Claims for Dairy Products (Chart)	22
Specific Requirements for Health Claims	23
Health Claim Based on Authoritative Statement	25
Qualified Health Claims	26

Structure/Function Claims

Overview/Definitions	27
Structure/Function, Disease and Authorized Health Claims (Chart)	27
Substantiation	28
Examples of Structure/Function Claims for Dairy Products	29

OTHER CLAIMS

■ Natural	30
■ Fresh	30
■ Organic	31
■ Recombinant Bovine Somatotropin (rbST)	32
■ Local	32

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY

Nutrient Fortification	33
Federal Standards of Identity for Dairy Foods	34
Grade 'A' Pasteurized Milk Ordinance	35
Processing and Nutrient Definitions	36
Product Naming	37
Ingredient Naming	40

OVERVIEW OF DAIRY PRODUCTS: NUTRITIONAL COMPOSITION (CHART)

Acknowledgment/Resources/Contact Information	43
--	----





REGULATORY OVERSIGHT

Marketing messages and claims promoted through multiple channels have oversight by both the Federal Trade Commission (FTC) and the U.S. Food and Drug Administration (FDA).

The FTC is responsible for protecting consumers from unfair or deceptive acts or practices and oversees food advertising. FTC's oversight broadly covers advertising materials, promotional activities, marketing and sales practices in general, and includes traditional print, television, telephone and radio advertising as well as materials provided on the Internet for the purposes of promoting the sale of a product.

FDA's oversight covers food labels and labeling, including nutrition claims. The label is the printed material upon a food's immediate container. Labeling refers to both labels and other printed material on any product container or wrapper (e.g., an outer carton, or a neck tag) or accompanying the food (e.g. shelf tags). FDA considers a website to be labeling if (1) the website address is given on the food label, or (2) the food product can be purchased from the website. FDA's nutrition labeling regulations apply primarily to food labels, whereas, nutrition claim regulations apply to both labels and labeling.

FDA's oversight of claims made on labels or in labeling is focused on (1) whether the claims are used in accordance with applicable regulations, and (2) whether the claims made for food products promote those products for use as a drug (e.g., juice for fighting colds and flu). FDA provides guidance to assist in determining when a statement is a disease claim, that is, a claim to diagnose, cure, mitigate, treat or prevent disease. The FTC focus in their oversight of product claims is whether claims are truthful and not misleading. FDA and FTC have both adopted the same "credible and reliable evidence" standard to ensure that the truthfulness of claims made is appropriately substantiated by scientific evidence.

Environmental marketing claims, which are overseen by the FTC, are applicable broadly across all types of communications, including advertisements, labels, package inserts, promotional materials, symbols, emblems, logos, depictions, product brand names and marketing through traditional, electronic and other media such as the Internet or email. FTC provides industry guidance, commonly known as the Green Guides. Revisions to update the guides, last updated in 1998, were proposed by FTC in October 2010. Some environmental related claims are also overseen by the U.S. Department of Agriculture (USDA), such as "organic" or the use of "natural" in labeling of meat, poultry and egg products.

Marketing claims may also be subject to actions from States Attorneys General complaints, Better Business Bureau's National Advertising Division (NAD) investigations, and competitor lawsuits under the Lanham Act for false advertising.

Useful Resources:

FDA Food Labeling & Nutrition: Guidance for Industry
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/default.htm>

FDA Guidelines for Structure/Function Claim Substantiation
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm>

FDA Structure/Function Claims, Small Entity Compliance Guide
 Guidance for Industry <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340.htm>

FTC Enforcement Policy Statement on Food Advertising
<http://www.ftc.gov/bcp/policystmt/ad-food.shtm>

FTC Dietary Supplement Advertising Guide for Industry
<http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm>

Guides for the Use of Environmental Marketing Claims (Green Guides) <http://www.ftc.gov/bcp/grnrule/guides980427.htm>

Complying with the Environmental Marketing Guides
<http://www.ftc.gov/bcp/edu/pubs/business/energy/bus42.shtm>

Sorting Out "Green" Advertising Claims
<http://www.ftc.gov/bcp/edu/pubs/consumer/general/gen02.shtm>

NUTRITION CLAIM BASICS

Overview of Nutrition Claims

This guide discusses the types of food label claims that when used to highlight the nutritional benefits of food products, must be used in accordance with FDA regulations. These claim categories are:

- ■ ■ Nutrient Content Claims
- ■ ■ Health Claims
- ■ ■ Structure/Function Claims

■ ■ ■ Nutrient Content Claims

Nutrient content claims are label statements that characterize the amount of a nutrient in a food. Nutrient content claims can highlight a product's strongest nutrition selling points. (More information on these claims can be found in the section "Nutrient Content Claims for Dairy Products.") Many dairy products are "excellent" or "good" sources of several vitamins and minerals, including calcium, phosphorus, potassium, riboflavin (vitamin B₂), vitamin B₁₂, vitamins A and D, and protein. Unlike many other food choices, dairy products are nutrient-dense and deliver substantial nutritional value. The FDA's nutrient content claim regulations provide many opportunities that allow food labels to communicate a particular nutritional value contained in dairy products:

- "Excellent Source" if the product contains 20% or more of the Daily Value (DV) per reference amount (see explanation of reference amounts below) for that nutrient
- "Good Source" if the product contains 10% to 19% of the DV per reference amount for that nutrient
- "Supplies __% of the DV of ____."
- "Added/Fortified" if the product contains at least 10% of the DV more than another food

Also, keep in mind there are allowable synonyms for these claims. Descriptors such as "high in" or "rich in" in lieu of "excellent source" provide some creative leeway.

While FDA nutrition labeling regulations place less emphasis on the nutrients designated as "other vitamins and minerals," these nutrients may be of special interest to certain segments of the population. If a product is targeted to these segments, using nutrient content claims may help position dairy products based on their full nutritional value.

Dairy products can also be modified to reduce the amount of certain components such as fat, saturated fat, sodium, cholesterol or calories to meet consumer needs and preferences. FDA regulations provide for certain descriptors such as "reduced," "light" and "low" to describe the nutritionally modified product.

■ ■ ■ Health Claims

Health claims describe a relationship between a food or food component in reducing the risk of a disease or health-related condition. FDA has approved a number of health claims for use on food labels (<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/default.htm>). The good news for certain dairy products is that the link between calcium and vitamin D and prevention of osteoporosis, a bone disease that is a major cause of disability in the United States, is one of the claims allowed and one that many dairy products qualify for. Other health claims that certain dairy products may qualify for include those related to: sodium and hypertension, potassium and blood pressure, fat and cancer, and saturated fat and coronary heart disease. In general, dairy products that typically qualify for health claims are those lower in fat, such as low-fat and fat-free milk, yogurt and other dairy products. For more information, see the section on "Health Claims."

Structure/Function Claims

The third category of FDA-regulated food label claims is known as “structure/function claims.” These claims describe the effect of a nutrient or substance on the normal structure or function of the body (e.g., calcium builds strong bones) or on general well-being. Unlike health claims, structure/function claims may be used on food products without prior FDA approval. However, like all other information on a food label, structure/function claims must be truthful and not misleading. For a structure/function claim to be truthful, manufacturers making a claim must have credible scientific evidence to substantiate the claims they make.

‘Reference Amount Customarily Consumed per Eating Occasion (reference amount)’ and ‘Label Serving Size’

For the purpose of nutrition labeling (e.g., the Nutrition Facts box information), nutrient amounts are declared for one serving of the food. The “Serving size” is calculated by the manufacturer of a packaged food based on a standardized reference amount of food customarily consumed per eating occasion for that food category [21 CFR 101.9(b)(1)]. The FDA has established by regulation “Reference Amounts Customarily Consumed” (reference amounts) for more than 130 food product categories [21 CFR 101.12(b)]. The serving size may, or may not, be the same as the reference amount. The reference amounts reflect the average amount of food customarily consumed in one eating occasion by people older than 4 years of age and are derived from national food consumption survey data. These reference amounts are the starting point for determining the serving size to be declared on the food label and are used to determine whether a product meets the criteria for a nutrition claim. The reference amounts for various dairy products are summarized in the table below.

Most food label claims are based on the reference amount (i.e., High is defined as at least 20% of the DV per reference amount). In most cases, foods with a small reference amount (less than or equal to either 30 g or 2 tablespoons) must meet the requirements of a content claim based on 50 g of the product, rather than per reference amount. This mostly impacts cheese products. Some nutrient content claims (e.g., Free) require a food to meet the claim criteria both on a per reference amount and a per labeled serving basis.

REFERENCE AMOUNTS CUSTOMARILY CONSUMED FOR VARIOUS DAIRY PRODUCTS		
Product	Reference Amount	Suggested Serving Size Statement Format Examples*
Milk and milk-based drinks	240 mL	8 fl oz (240 mL)
Cheeses (e.g., Cheddar, Swiss and American), including cubes, slices and shreds	30 g	1 oz (28 g) 1 slice (21 g) ¼ cup (26 g)
Cottage cheese	110 g	½ cup (124 g)
Cheese used primarily as ingredients (e.g., dry cottage cheese and ricotta cheese)	55 g	¼ cup (62 g)
Cheese, grated hard (e.g., Parmesan and Romano)	5 g	1 tbsp (5 g)
Cream cheese, sour cream and cheese spreads	30 g	2 tbsp (28 g)
Yogurt	225 g	1 cup (227 g)
Butter	1 tbsp	1 tbsp (14 g)

*Use common household measures (cup, tablespoon, piece, slice, etc.) as the FDA requires serving sizes to be listed in both metric and common household measures. The FDA allows the rounding of ounces and household measures for servings of products such as cheese sticks and slices that are close to the approved reference amount.

■ ■ ■ 'Disclosure Statements' and 'Disqualifying Levels'

A "disclosure statement" is required when a nutrient content claim is made and the food contains one or more of the following nutrients in excess of the level listed below. Exceeding one or more of these nutrient levels disqualifies a food from most FDA-approved health claims (although there are some exceptions). For more information, see the section on "Health Claims."

DISCLOSURE/DISQUALIFYING NUTRIENTS	DISCLOSURE/DISQUALIFYING LEVEL
Total fat	13 g
Saturated fat	4 g
Cholesterol	60 mg
Sodium	480 mg

The required disclosure statement is: "See nutrition information for [nutrient requiring disclosure] content." The disclosure requirement is triggered by exceeding the disclosure levels per reference amount, per labeled serving or per 50 g for foods with a small reference amount. These disclosure/disqualifying nutrient levels apply to individual foods; the levels are different for meal and main dish products. Detailed information on the requirements for the disclosure statement can be found in the nutrient content section of the FDA "*The Food Labeling Guide*" at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm064908.htm> or [21 CFR 101.13(h)(1)-(3)].

The disclosure statement must appear prominently and in immediate proximity to the claim with no intervening material. If the claim appears on more than one panel, the disclosure statement must accompany it except when the claim appears on the panel that bears the nutrition information, in which case the disclosure statement may be excluded.

■ ■ ■ Daily Values Used on the Nutrition Facts Panel

The Daily Value (DV) is a reference value intended to facilitate comparisons of the nutritional value of different foods. Although commonly thought of as a "daily intake requirement" that is not the purpose of the DVs. The DVs were derived from dietary intake recommendations so they would be realistic average daily diet values, but they are not daily nutrient requirements. Used as "reference values" it is easier for consumers to recognize that 100 mg calcium per serving (10% DV) is a good source of calcium whereas 100 mg of sodium per serving (4% DV) is a relatively low amount of sodium.

Mandatory (boldface) and voluntary nutrients for nutrition labeling and their Daily Values are listed below. Note that Daily Values have not been set for trans fat or sugar.

NUTRIENTS AND DAILY VALUES USED ON THE NUTRITION FACTS PANEL		
Nutrient (mandatory nutrients are in boldface)	Unit Of Measure	Daily Values*
Total fat	grams (g)	65
Saturated fat	grams (g)	20
Trans fat	grams (g)	(no DV)
Cholesterol	milligrams (mg)	300
Sodium	milligrams (mg)	2,400
Potassium	milligrams (mg)	3,500
Total carbohydrate	grams (g)	300
Sugars	grams (g)	(no DV)
Dietary Fiber	grams (g)	25
Protein	grams (g)	50
Vitamin A	International Unit (IU)	5,000
Vitamin C	milligrams (mg)	60
Calcium	milligrams (mg)	1,000
Iron	milligrams (mg)	18
Vitamin D	International Unit (IU)	400
Vitamin E	International Unit (IU)	30
Vitamin K	micrograms (µg)	80
Thiamin	milligrams (mg)	1.5
Riboflavin	milligrams (mg)	1.7
Niacin	milligrams (mg)	20
Vitamin B ₆	milligrams (mg)	2.0
Folate	micrograms (µg)	400
Vitamin B ₁₂	micrograms (µg)	6.0
Biotin	micrograms (µg)	300
Pantothenic acid	milligrams (mg)	10
Phosphorus	milligrams (mg)	1,000
Iodine	micrograms (µg)	150
Magnesium	milligrams (mg)	400
Zinc	milligrams (mg)	15
Selenium	micrograms (µg)	70
Copper	milligrams (mg)	2.0
Manganese	milligrams (mg)	2.0
Chromium	micrograms (µg)	120
Molybdenum	micrograms (µg)	75
Chloride	milligrams (mg)	3,400

Nutrients in this table are listed in the order specified by regulations on a label in accordance with 21 CFR 101.9(c). This list includes only those nutrients for which a Daily Reference Value (DRV) has been established in 21 CFR 101.9(c)(9) or a Reference Daily Intake (RDI) in 21 CFR 101.9(c)(8)(iv).

*Based on intake of 2,000 calories daily.

NUTRIENT CONTENT CLAIMS

Overview/Definitions

A nutrient content claim on a food product characterizes how much of a specific nutrient is in that food. It does not link that nutrient with a specific disease or health-related condition. Nutrient content claims can only be made if a food product meets the criteria for a content claim set by the FDA. Here are some of the most frequently used types of nutrient content claims.

■ ■ ■ Absolute Nutrient Content Claims

Absolute nutrient content claims refer to a specific nutrient level in a single food. These types of claims, like “high in calcium” or “low in fat” do not make comparisons to any other food. The meaning of the descriptive terms used in absolute claims (e.g., free, low, very low (sodium only), high, good source) are defined in FDA’s nutrient content claim regulations.

Also common are claims referring to “percentage” or “amount.” The FDA specifically defines the terms and approved synonyms in conjunction with specific nutrients. The following charts show examples of absolute nutrient content claims for select dairy products.

‘High’ and ‘Good Source’ Claims

The terms “high” and “good source” and their synonyms are often used on food products containing significant levels of protein, vitamins, minerals or dietary fiber. A “high” claim (or “rich in” or “excellent source of”), such as “Milk: an excellent source of calcium,” may be used when a food contains at least 20% of the DV of the nutrient per reference amount. A “good source” claim (or “contains” or “provides”), such as “Milk: a good source of potassium,” may be used when the claimed nutrient is present in the food between 10% and 19% of the DV per reference amount. See chart for examples of select dairy products that may qualify for “high” or “good source” claims.

■ ■ ■ Relative Nutrient Content Claims

A relative claim is one that describes the level of a nutrient in one food relative to the level in another food,” such as “50% less fat than regular cheese.” Descriptor terms frequently used as relative claims are: “light,” “lite,” “reduced,” “less” or “more.” In “light” and “reduced” claims the comparison must be for similar foods; for example, reduced-fat Swiss cheese would be compared with regular Swiss cheese, or lite cream cheese with regular cream cheese. For the “more” and “less” claims the comparison may be between either similar foods or dissimilar foods within the same product category (e.g., potato chips and pretzels are dissimilar foods but are both snacks). The nutrient levels used for the comparison foods may come from a valid database, an average of the top three brands, a market leader, a manufacturer’s regular product or a competitor’s product. However, the comparison food nutrient levels for a “light” claim can only be the marketplace norm for that food and cannot be from a single product, such as a company’s regular product.

The following comparative statements must accompany all relative claims:

- Identity of the comparison food and the percentage (or fraction) of nutrient difference between the product and the comparison food (e.g., 50% less fat than [comparison food], or 1/3 fewer calories than [comparison food])
- Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the comparison food (e.g., fat content has been reduced from ___ g to ___ g per serving).

See charts for examples of relative nutrient content claims for select dairy products.

'More' Claims

Claims with descriptive terms such as “more,” “fortified,” “enriched,” “added,” “extra” and “plus” are relative claims that may be used to describe the level of protein, vitamins, minerals or dietary fiber present in an individual food. Foods using these claims must contain at least 10% more of the DV of the nutrient per reference amount than is found in an appropriate comparison food. For “fortified,” “enriched” or “added” the comparison food must be a similar food (e.g., enriched yogurt compared with regular yogurt). For “more” claims, the comparison food may be a dissimilar food in the same category (e.g., milk with more calcium compared with orange juice).

The “more” claims, because they are relative claims, must be accompanied with information about the percentage (or fractional) nutrient amount difference from the comparison food, and the levels of the nutrient in both foods. For example: “Contains twice the calcium as regular cottage cheese.” would be accompanied with “contains 170 mg calcium per serving,” which is 10% more of the DV for calcium, compared with 70 mg per serving in regular cottage cheese. Where a “more” claim refers to a nutrient that has been added to the food, adding the nutrient must be in accordance with FDA’s Fortification Policy. The Fortification Policy establishes a uniform set of principles for the rational addition of nutrients to foods. See also the “Nutrient Fortification” section.

'Reduced' Claims

A “reduced” claim provides marketing opportunities for dairy products specifically formulated to decrease the amount of fat, saturated fat, sodium, cholesterol, calories or sugars. To use a “reduced” claim, there must be at least a 25% reduction per reference amount for the nutrient. “Less” and “lower” may be used as synonyms for “reduced.” “Fewer” may be used as a synonym in reduced calorie claims. “Reduced” claims are required to be accompanied by the same comparative information of other relative claims (see “Relative Nutrient Content Claims Section”). For example, a lower-fat Swiss cheese might label as: “Reduced-fat Swiss Cheese. 37% less fat than our regular Swiss Cheese. Reduced-fat Swiss 5 g fat per serving, regular Swiss cheese 8 g fat per serving.

'Light' or 'Lite' Claims

“Light” claims are also relative claims. The terms “light” and “lite,” with regard to calories, fat or sodium, are permitted to describe an individual food under specific conditions as summarized on the chart.

■ ■ ■ Implied Nutrient Content Claims

Implied nutrient content claims are label statements, other than those claims defined in FDA regulations, that implicitly characterize the level of a nutrient or imply that because of its nutrient content, the food is useful in maintaining healthy dietary practice. Implied nutrient content claims may be used on food labels provided the food meets the regulatory criteria established for the claim that is implied. The FDA will determine on a case-by-case basis whether a product label bears an implied nutrient content claim.

'Label Statements That Are Implied Claims'

The FDA has identified the following types of statements as being implied nutrient content claims:

- A claim that suggests a nutrient is absent or present in a certain amount is an implied nutrient content claim (e.g., "high in oat bran" is a claim about an ingredient that implies the food is high in dietary fiber).
- A product name that includes the name of a characterizing ingredient associated with a nutritional benefit is an implied nutrient content claim. For example, using oat bran in the name of a food, e.g., "oat bran muffins," implies that the food is a good source of dietary fiber.
- A phrase such as "as much [nutrient] as a [food]" is an implied nutrient content claim. The "as much as" type of implied claims may be used provided both the labeled food and the comparison food qualify as a good source of the nutrient.

'Healthy'

"Healthy" and all variations of the word "health" is a specific FDA-defined implied nutrient content claim. "Healthy" implies that a food does not contain any "unhealthy" levels of nutrients. A food labeled as "healthy" must qualify as both "low total fat" and "low saturated fat," and may not exceed the nutrient content claims disclosure levels for cholesterol and sodium. These criteria must be met both per reference amount and per labeled serving, and a food with a small reference amount must meet the criteria per 50 g of food. Additionally, the food must contain at least 10% of the DV per reference amount for one or more of vitamin A, vitamin C, calcium, iron, protein or fiber. The chart on page 20 provides a partial list of selected dairy products that may qualify.

■ ■ ■ Numeric Declaration Nutrient Content Claims

The FDA permits the use of factual quantitative statements that disclose the amount of a nutrient in a product (e.g., 100 calories or 5 g of fat) provided that such a statement does not implicitly characterize the level of a nutrient and is not false or misleading. This provision was intended as a way for manufacturers to present quantitative information about nutrients that do not have established DVs. For example, there is no established DV for lactose.

A statement about a nutrient amount or percentage that implicitly characterizes the level of the nutrient is permitted if the food either qualifies for the implied claim or the statement accompanied by a disclaimer that the food is not “low” or a “good source” (as appropriate) of that nutrient. For example, “Only X g of fat” implies that the X g is a small amount of fat. This claim is permissible only if (1) the food meets the “low fat” criteria, or (2) the food does not meet the “low fat” criteria and the claim is immediately followed by: “Not a low-fat food.”

■ ■ ■ General Requirements for Nutrient Content Claims

When making a nutrient content claim for a qualifying product, keep the following general requirements in mind:

- Dairy products making a nutrient content claim must carry nutrition labeling.
- Most nutrient content claim criteria are based on the reference amount rather than the label serving size (see section on reference amounts).
- The type size used for nutrient content claims may not be larger than twice that of the product name.
- When a disclosure statement is required, it must be placed close to the nutrient content claim (see “Disclosure Statements and Disqualifying Levels” section).
- Protein content claims trigger the need to list protein % DV in the Nutrition Facts box.
- Relative nutrient content claims must be accompanied by comparative information about both the labeled food and the reference food.
- Relative nutrient content claims about added nutrients can only be used if the fortification is in accordance with the FDA Fortification Policy.

■ ■ ■ Examples of Claims for Select Dairy Products

The charts on pages 11-20 outline the main nutrient content claims, both absolute and relative, that can be considered for use on selected dairy products. The charts include:

- Descriptors and synonyms that the FDA has defined for specific nutrient content claims. Disclosure statements will be required for some products (see “Disclosure Statements” and “Disqualifying Levels” section).
- Definitions and criteria the food must meet in order to use a specific descriptor or synonym.
- Selected dairy products that may qualify for this claim.

EXAMPLES OF DAIRY PRODUCTS THAT MAY QUALIFY FOR 'HIGH' OR 'GOOD SOURCE' CLAIMS*

	Reference Amount	High** Excellent Source Rich In	Good Source*** Provides Contains
Fluid Milk			
Whole milk, vitamins A & D added	240 mL	Calcium Vitamin D Riboflavin Phosphorus	Vitamin B ₁₂ Protein
Reduced-fat milk, vitamins A & D added (2% milk fat)	240 mL	Calcium Vitamin D Riboflavin Phosphorus Vitamin B ₁₂	Vitamin A Potassium Protein
Low-fat milk, vitamins A & D added (1% milk fat)	240 mL	Calcium Vitamin D Riboflavin Phosphorus Vitamin B ₁₂	Vitamin A Potassium Protein
Fat-free (skim), vitamins A & D added	240 mL	Calcium Vitamin D Riboflavin Phosphorus Vitamin B ₁₂	Vitamin A Potassium Protein
Yogurt			
Whole milk, plain	225 g	Calcium Riboflavin Phosphorus	Potassium Protein Zinc
Low-fat, plain (1.5% milk fat)	225 g	Calcium Riboflavin Phosphorus Protein	Potassium
Fat-free, plain	225 g	Calcium Riboflavin Phosphorus Protein	Potassium Zinc
Cottage Cheese			
Cottage cheese, creamed (4% milk fat)	110 g	Protein Phosphorus	Riboflavin
Low-fat cottage cheese (2% milk fat)	110 g	Protein Phosphorus	Riboflavin
Low-fat cottage cheese (1% milk fat)	110 g	Protein	Riboflavin Phosphorus

*Claims based on values taken from the U.S. Department of Agriculture, Agricultural Research Service, 2010, USDA National Nutrient Database for Standard Reference, Release 23. Nutrient Data Laboratory Home Page: <http://www.ars.usda.gov/nutrientdata>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only.

NOTE: Consult the Code of Federal Regulations for specific nutrition labeling requirements for making nutrient content claims.

** Contains 20% or more of the DV per reference amount.

*** Contains 10% to 19% of the DV per reference amount.

EXAMPLES OF DAIRY PRODUCTS THAT MAY QUALIFY FOR 'HIGH' OR 'GOOD SOURCE' CLAIMS*

	Reference Amount	High** Excellent Source Rich In	Good Source*** Provides Contains
Cheese			
Pasteurized Process American cheese food	30 g	Phosphorus	Calcium Protein
Pasteurized process American cheese	30 g		Calcium Protein Phosphorus
Blue	30 g		Calcium Phosphorus Protein
Brick	30 g		Calcium Phosphorus Protein
Cheddar	30 g	Calcium	Phosphorus Protein
Colby	30 g	Calcium	Phosphorus Protein
Edam	30 g	Calcium	Phosphorus Protein
Gouda	30 g	Calcium	Phosphorus Protein
Monterey Jack	30 g	Calcium	Phosphorus Protein
Mozzarella, whole milk	30 g		Calcium Phosphorus Protein Vitamin B ₁₂
Mozzarella, low moisture, part skim	30 g	Calcium	Phosphorus Protein Vitamin B ₁₂
Muenster	30 g	Calcium	Phosphorus Protein
Provolone	30 g	Calcium	Phosphorus Protein
Ricotta	55 g		Calcium Phosphorus Protein
Swiss	30 g	Calcium	Phosphorus Protein Vitamin B ₁₂

*Claims based on values taken from the U.S. Department of Agriculture, Agricultural Research Service, 2010, USDA National Nutrient Database for Standard Reference, Release 23. Nutrient Data Laboratory Home Page: <http://www.ars.usda.gov/nutrientdata>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only.

NOTE: Consult the Code of Federal Regulations for specific nutrition labeling requirements for making nutrient content claims.

** Contains 20% or more of the DV per reference amount.

*** Contains 10% to 19% of the DV per reference amount.

FAT AND SATURATED FAT CLAIMS

Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Fat-free	<ul style="list-style-type: none"> - Free of fat - Fat-free - Trivial source of fat - Zero fat - Without fat- Skim (milk only) 	Less than 0.5 g total fat per reference amount and per labeled serving size. No added fat unless ingredient declaration lists a fat-containing ingredient followed by an asterisk and the statement "Adds a trivial amount of fat."	1, 3	<ul style="list-style-type: none"> - Fat-free milk - Fat-free yogurt
Low-fat	<ul style="list-style-type: none"> - Low in fat - Low source of fat - Little fat - Contains a small amount of fat 	Maximum of 3 g total fat per reference amount (when reference amount is greater than 30 g or 2 tbsp).	1, 3	<ul style="list-style-type: none"> - Low-fat milk (1% milk fat) - Low-fat yogurt - Low-fat cottage cheese (1% and 2% milk fat)
		Maximum of 3 g total fat per reference amount and per 50 g (when the reference amount is 30 g or less, or 2 tbsp or less).	1, 3	Few dairy products at this reference amount could make this claim unless specifically reformulated
Reduced-fat	<ul style="list-style-type: none"> - Reduced in fat - Fat reduced - Less fat - Lower fat - Lower in fat 	At least a 25% reduction in total fat per reference amount in comparison to a comparison food. Claim cannot be made if comparison food meets definition for "low-fat."	1, 2	<ul style="list-style-type: none"> - Reduced-fat milk (2% milk fat) - Many of the "reduced-fat" and "light" cheeses, butters and other dairy products
Percent fat-free	- ___% fat-free	May be used if the product meets the requirements for "low-fat."	1, 3	<ul style="list-style-type: none"> - Low-fat milk (1% milk fat) - Low-fat yogurt - Low-fat cottage cheese (1% and 2% milk fat)
	- 100% fat-free	"100% fat-free" can only be used on "fat-free" foods that contain less than 0.5 g of fat per 100 g and contain no added fat.	1, 3	<ul style="list-style-type: none"> - Fat-free milk - Fat-free yogurt
Saturated fat-free	<ul style="list-style-type: none"> - Free of saturated fat - No saturated fat - Trivial source of saturated fat - Without saturated fat 	Less than 0.5 g saturated fat and less than 0.5 trans fatty acids per reference amount and per labeled serving size. The food may not contain any ingredient that is a saturated fatty acid or is generally understood by consumers to contain saturated fat unless the ingredient, as declared in the ingredient statement, is accompanied by an asterisk that refers consumers to the statement "Adds a trivial amount of saturated fat" or similar specified statement. Manufacturers must disclose the level of total fat and cholesterol in immediate proximity to a saturated fat content claim. Disclosure of cholesterol and fat is unnecessary if the food contains (per reference amount) less than 2 mg of cholesterol and 0.5 g fat.	1, 3	<ul style="list-style-type: none"> - Fat-free milk - Fat-free yogurt - Fat-free cottage cheese

FAT AND SATURATED FAT CLAIMS

Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Low in saturated fat	<ul style="list-style-type: none"> - Low saturated fat - Low source of saturated fat - Little saturated fat - Contains a small amount of saturated fat 	Contains 1 g or less of saturated fatty acids per reference amount and derives no more than 15% of calories from saturated fatty acids.	1, 3	<ul style="list-style-type: none"> - Low-fat cottage cheese (1% milk fat) - Orange sherbet
Reduced in saturated fat	<ul style="list-style-type: none"> - Reduced saturated fat - Lower saturated fat - Less saturated fat 	At least a 25% reduction in saturated fat per reference amount compared with an appropriate comparison food.	1, 2	<ul style="list-style-type: none"> - Reduced-fat milk (2% milk fat) - Low-fat milk (1% milk fat) - Low-fat yogurt - Some low-fat reduced-fat cheeses on the market

***Required Statements**

1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."
2. For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required), for a product making relative claims – such as "light," "reduced," "less," "fewer" or "lower" – comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For example: "Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving."
3. For "low" and "free" claim only: If a food is "low in" or "free of" a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently "low in" or "free of" whatever nutrient is being claimed for that product. For example: "Whole milk – a low-sodium food."

CHOLESTEROL CLAIMS				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions	Required Statements*	Examples of Eligible Dairy Products
Cholesterol-free	<ul style="list-style-type: none"> - Free of cholesterol - Zero cholesterol - Without cholesterol - No cholesterol - Trivial source of cholesterol 	<p>Contains 2 mg or less of cholesterol per reference amount and per serving size on label. Contains 2 g or less of saturated fat per reference amount.</p> <p>The food contains no ingredient that is generally understood by consumers to contain cholesterol unless the ingredient, as declared in the ingredient statement, is accompanied by an asterisk that refers consumers to the statement "Adds a trivial amount of cholesterol" or similar specified statement.</p>	1, 3	
Low cholesterol	<ul style="list-style-type: none"> - Low in cholesterol - Contains a small amount of cholesterol - Low source of cholesterol 	<p>Maximum of 20 mg cholesterol per reference amount and per 50 g of food if reference amount is 30 g or less.</p> <p>Maximum 2 g saturated fat per reference amount (when reference amount is greater than 30 g or 2 tbsp).</p>	1, 3, 4	<ul style="list-style-type: none"> - Skim milk - Low-fat milk (1% milk fat) - Fat-free yogurt - Fat-free frozen yogurt - Low-fat yogurt - Low-fat cottage cheese (1% and 2% milk fat) - Fat-free, pasteurized, processed cheese
Reduced cholesterol	<ul style="list-style-type: none"> - Reduced cholesterol - Lower cholesterol - Less cholesterol 	<p>At least a 25% reduction in cholesterol per reference amount compared with an appropriate comparison food. Contains 2 g or less of saturated fat per reference amount.</p> <p>Claim not permitted if the comparison food meets the definition of "low cholesterol" claim.</p>	1, 2	<ul style="list-style-type: none"> - Low-fat cottage cheese (1% milk fat) compared with low-fat cottage cheese (2% milk fat) - Low-fat cottage cheese (2% milk fat) compared with full-fat cottage cheese

*** Required Statements**

1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."
2. For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required), for a product making relative claims – such as "light," "reduced," "less," "fewer" or "lower" – comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food to the comparison food per labeled serving. For example: "Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving."
3. For "low" and "free" claim only: If a food is "low in" or "free of" a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently "low in" or "free of" whatever nutrient is being claimed for that product. For example: "Whole milk – a low-sodium food."
4. If total fat exceeds 13 g per reference amount (or per 50 g when reference amount is 30 g or less, or 2 tbsp or less), the food must declare the total amount of fat in a serving next to the cholesterol claim.

SODIUM CLAIMS

Claim	Nutrient Descriptors and Synonyms	FDA Definitions	Required Statements*	Examples of Eligible Dairy Products
Sodium-free	<ul style="list-style-type: none"> - Salt-free - Free of sodium - No sodium - Zero sodium - Without sodium - Trivial source of sodium 	Less than 5 mg sodium per reference amount. No added sodium or ingredients containing sodium unless the ingredient is followed by an asterisk and the statement "Adds a trivial amount of sodium."	1, 3	
Very low sodium	<ul style="list-style-type: none"> - Very low in sodium 	Maximum of 35 mg of sodium per reference amount and per 50 g (when reference amount is 30 g or less, or 2 tbsp or less).	1, 3	<ul style="list-style-type: none"> - Light whipping cream - Heavy cream - Light cream
Low sodium	<ul style="list-style-type: none"> - Little sodium - Low source of sodium - Contains a small amount of sodium - Low in sodium 	Maximum of 140 mg of sodium per reference amount and per 50 g (when reference amount is 30 g or less, or 2 tbsp or less).	1, 3	<ul style="list-style-type: none"> - All fluid white milk - Sour cream - Ice cream - Half-and-half - Swiss cheese
Reduced in sodium	<ul style="list-style-type: none"> - Reduced sodium - Reduced in sodium - Sodium reduced - Less sodium - Lower sodium - Lower in sodium 	At least a 25% reduction in sodium per reference amount compared with an appropriate comparison food. Claim cannot be made if comparison food meets definition for "low sodium."	1, 2	<ul style="list-style-type: none"> - Some reduced-sodium cheeses
Light in sodium		Comparison food contains more than 40 calories or more than 3 g of fat per reference amount and is reduced in sodium by 50% or more. Cannot be made if the comparison food meets the definition of "low sodium."	1, 2	<ul style="list-style-type: none"> - Any dairy product with a 50% reduction in sodium content would qualify; e.g., "light-in-sodium cottage cheese," "light-in-sodium Pasteurized process American cheese."

NOTE: The FDA does not consider "salt" a synonym for "sodium," although it permits the term "salt-free" if the food qualifies for the definition of "sodium-free." The claim "low salt" has not been defined and cannot be used on the food label.

* Required Statements

1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."
2. For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required), for a product making relative claims – such as "light," "reduced," "less," "fewer" or "lower" – comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food to the comparison food per labeled serving. For example: "Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving."
3. For "low" and "free" claim only: If a food is "low in" or "free of" a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently "low in" or "free of" whatever nutrient is being claimed for that product. For example: "Whole milk – a low-sodium food."

SUGAR CLAIMS				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Sugar-free	Sugar-free Free of sugar No sugar Zero sugar Without sugar Sugarless Trivial source of sugar Negligible source of sugar Insignificant amount of sugar	The food contains less than 0.5 g sugars per reference amount and per labeled serving. The food contains no ingredient that is sugar. The food is labeled <i>Low Calorie</i> or <i>Reduced Calorie</i> , or else the sugar-free claim be accompanied by <i>not a low-calorie food</i> , or <i>not a reduced-calorie food</i> , or <i>not for weight control</i> .	1, 3, 4	
No added sugar	No added sugar Without added sugar No sugar added	No amount of sugars or ingredient that contains sugars is added during processing or packaging. The food does not contain an ingredient containing added sugars. The sugars content of the food has not been increased by some means such as the use of enzymes, unless a functionally insignificant increase in sugar results. The food for which the “no sugar added” food is a substitute normally contains added sugar. The food is either a <i>low-calorie</i> or <i>reduced-calorie food</i> , or bears a <i>not a low-calorie food</i> (or <i>not a reduced-calorie food</i>) statement, and a statement to “see nutrition information for further information on sugar and calorie content.”	1	
Reduced sugar	Reduced sugar Reduced in sugar Sugar reduced Less sugar Lower sugar Lower in sugar	The food contains at least 25% less sugar per reference amount than an appropriate reference food.	1, 2	

*** Required Statements**

1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): “See nutrition information for [nutrient(s) requiring disclosure] content.”
2. For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required) for a product making relative claims – such as “light,” “reduced,” “less,” “fewer” or “lower” – comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For example: “Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving.”
3. If the food contains an ingredient generally understood by consumers to contain sugar, the listing of that ingredient in the Ingredient List must have an asterisk referencing an “*adds a negligible amount of sugar” statement that follows the ingredient list.
4. If the food has not been specially processed or formulated to remove sugar, the claim must be accompanied by the statement “a sugar-free food.”

CALORIE CLAIMS				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Calorie-free	<ul style="list-style-type: none"> - Calorie-free - No calories - Zero calories - Free of calories - Without calories 	The food contains less than 5 calories per reference amount and per labeled serving [21 CFR 101.60].	1, 3	
Low calorie	<ul style="list-style-type: none"> - Few calories - Contains a small amount of calories - Low source of calories - Low in calories 	40 calories or less per reference amount (and per 50 g if reference amount is 30 g or less).	1, 3	
Reduced calorie	<ul style="list-style-type: none"> - Reduced in calories - Calorie reduced - Fewer calories 	<p>Minimum of 25% reduction in calories per reference amount compared with an appropriate comparison food.</p> <p>Cannot be made if comparison food meets the definition of "low calorie."</p>	1, 2	<p>Products formulated using less sugar and fat, such as reformulated:</p> <ul style="list-style-type: none"> - Ice cream - Yogurts - Frozen yogurts - Flavored milk

*** Required Statements**

1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."
2. For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required) for a product making relative claims – such as "light," "reduced," "less," "fewer" or "lower" – comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For example: "Contains 25% less fat than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g per serving."
3. For "low" and "free" claim only: If a food is "low in" or "free of" a nutrient because it is inherent to the product, a statement must be included to show that not just one particular brand but all products of that type are inherently "low in" or "free of" whatever nutrient is being claimed for that product. For example: "Whole milk – a low-sodium food."

'LIGHT' OR 'LITE' CLAIMS				
Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Examples of Eligible Dairy Products
Light or lite (fat or calories)	- Light or lite	<p>If the food derives less than 50% of its calories from fat, the number of calories must be reduced by at least 1/3 per reference amount compared with an appropriate comparison food or its fat content must be reduced by 50% or more per reference amount compared with the comparison food. Cannot be made if comparison food meets definition of "low fat" or "low calorie."</p> <p>If the food derives 50% or more of its calories from fat, its fat content must be reduced by 50% or more per reference amount compared with an appropriate comparison food. Cannot be made if comparison food meets definition of "low fat" or "low calorie."</p>	1, 2	Reformulated ice cream, yogurts and frozen yogurts using artificial sweeteners or fat substitutes
Light or lite (sodium)	- Light or lite (sodium)	Without further qualification, this term is permitted to highlight reductions in sodium content if the sodium content is reduced by 50% or more and the comparison food contains 40 calories or less and 3 g fat or less per reference amount.	1, 2	
<p>NOTE: Non-nutrient uses of the term "light" still can be used to describe the physical properties of the food product such as texture, color and flavor as long as the label explains the intent – for example, "light in color" and "light and fluffy texture."</p> <p>Also, if a manufacturer can demonstrate that the term "light" has been associated, through common use, with a particular food to reflect a physical or sensory attribute (e.g., light brown sugar) and has become part of the statement of identity, "light" may be used without a reduction in fat or calories [21 CFR 101.56].</p>				
<p>* Required Statements</p> <p>1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."</p> <p>2. For relative claims only: In addition to a disclosure statement identifying disqualifying nutrients (if required) for a product making relative claims – such as "light," "reduced," "less," "fewer" or "lower" – comparative information must also follow that identifies: 1) the comparison food; 2) the percentage or fraction by which the amount was reduced; and 3) quantitative information comparing the amount of the nutrient in the food with the comparison food per labeled serving. For "light" claims, comparative information must be provided for both fat and calories. For example: "Contains 25% less fat and 20% fewer calories than our regular Swiss cheese. Fat has been reduced from 8 g to 6 g, and calories have been reduced from 100 to 80 per serving."</p>				

HEALTHY CLAIMS

Claim	Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Partial List of Eligible Dairy Products
Healthy	<ul style="list-style-type: none"> - Health - Healthful - Healthfully - Healthfulness - Healthier - Healthiest - Healthily - Healthiness 	<p>Must meet the definition of "low" fat and saturated fat, and neither cholesterol nor sodium may be present at a level exceeding the disclosure levels per reference amount and per 50 g for foods with reference amounts 30 g or less.</p> <p>Contains at least 10% of the DV per reference amount for one or more of: vitamin A, vitamin C, calcium, iron, protein or fiber.</p>	<ul style="list-style-type: none"> - Low-fat cottage cheese (1% milk fat) - Fat-free milk - Fat-free yogurt

NUMERIC DECLARATION CLAIMS

Nutrient Descriptors and Synonyms	FDA Definitions and Criteria	Required Statements*	Partial List of Eligible Dairy Products
<ul style="list-style-type: none"> - Percent - Amount 	The level of a nutrient in a product in absolute or percentage amounts.	1	<p>A number of dairy products can use this claim to describe the level of a particular nutrient, such as:</p> <ul style="list-style-type: none"> - Cheddar cheese: "20% of the DV for calcium" - Fat-free milk: "0 g of fat" - Fat-free milk: "0 g of saturated fat" - Low-fat yogurt: "30% of the DV for calcium" - Reduced-fat milk: "15% of the DV for protein"

*** Required Statements**

1. If the food bearing the claim exceeds the disqualifying levels of any of the following nutrients – total fat (13 g), saturated fat (4 g), cholesterol (60 mg) or sodium (480 mg) per reference amount or per 50 g as appropriate – a statement accompanying the most prominent claim is required to disclose the disqualifying nutrient(s): "See nutrition information for [nutrient(s) requiring disclosure] content."

HEALTH CLAIMS

Overview/Definitions

A health claim, by FDA definition, is any statement that characterizes – explicitly or by implication – the relationship of a substance in a food or dietary supplement to a disease or health-related condition [21 CFR 101.14(a)(1)]. There are three pathways through which new health claims become approved for use on food or dietary supplement labels.

- The 1990 Nutrition Labeling and Education Act (NLEA) allows the FDA to issue authorizing regulations for individual health claims for foods and dietary supplements after the FDA reviews the scientific evidence and concludes there is significant scientific agreement that the substance/disease relationship is supported by the totality of available scientific evidence.
- The 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims to become approved based on an Authoritative Statement of a scientific body of the U.S. government or the National Academy of Sciences; such health claims may be used after submission of a health claim notification to the FDA. For more information on these types of claims, see <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm>.
- The 2003 FDA Consumer Health Information for Better Nutrition Initiative provides for Qualified Health Claims where the quality and strength of the scientific evidence fall below the standard of “significant scientific agreement” required for the FDA to issue authorized health claims. For more information on these types of claims, see <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/default.htm>.

A “health claim,” by definition, has two essential components: (1) a substance (whether a food, food component or dietary ingredient); and (2) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim. For example, statements that address a role of dietary patterns or of general categories of foods (e.g., fruits and vegetables) in health are not considered to be health claims, provided that the context of the statement does not suggest that a specific substance is the subject of the statement. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are regulated as structure/function claims rather than as health claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health-related condition. Only the health claims are subject to FDA review and authorization.

The FDA has approved a number of health claims – by regulation (21 CFR 101.72 through 101.83), or through FDAMA authoritative statement-based claim notifications, or as Qualified Health Claims – that can be used on food products. See <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm>.

DIETARY COMPONENT	DISEASE OR HEALTH-RELATED CONDITION
Calcium and vitamin D	Osteoporosis (21 CFR 101.72)
Sodium	Hypertension (21 CFR 101.74)
Dietary fat	Cancer (21 CFR 101.73)
Saturated fat and cholesterol	Coronary heart disease (21 CFR 101.75)
Potassium	High blood pressure and stroke http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/ucm073606.htm

General Requirements for Health Claims

When the FDA issues a regulation for a health claim, the health claim is available to all companies, provided that:

- The food contains, without fortification, 10% or more of the DV per reference amount for one or more of the six nutrients shown in the table to the right. Health claims are not permitted on labels of foods that do not contain any of these nutrients at a level of at least 10% DV per reference amount.
- The food contains less than the “disqualifying” amount per reference amount for total fat, saturated fat, sodium and cholesterol (see section on “Disclosure statements” and “Disqualifying levels”). Some individual health claims have more, or less, restrictive specific requirements for these nutrients; for example foods bearing the sodium/hypertension health claim must be low in sodium. (See pages 23-26 for individual health claims and their specific nutrient requirements.)
- All information must be in one place without intervening material.
- The claim must frame the impact that intake, or reduced intake, might have on a disease or health-related condition in the context of a total dietary pattern.
- The claim helps the public understand the information provided and the significance of the information in the context of a total daily diet.
- The claim is complete, truthful and not misleading.
- The food is not represented for infants or toddlers younger than 2 years of age.
- The claim uses “may” or “might” to express the relationship between a substance and a disease.
- The claim does not quantify any degree of risk reduction.
- The claim indicates that disease depends on many factors.

10% of Daily Value (DV)	
Vitamin A	500 IU
Vitamin C	6 mg
Iron	1.8 mg
Calcium	100 mg
Protein	5 g
Fiber	2.5 g

POTENTIAL HEALTH CLAIMS FOR DAIRY PRODUCTS*								
Health Claim**	Milk			Yogurt		Cottage Cheese		
	Reduced-fat (2% milk fat)	Low-fat (1% milk fat)	Fat-free (skim)	Plain (low-fat)	Plain (fat-free)	2% milk fat	1% milk fat	Fat-free
Calcium, vitamin D and osteoporosis	Yes	Yes	Yes	Yes	Yes	No	No	No
Sodium and hypertension	Yes	Yes	Yes	No	No	No	No	No
Dietary fat and cancer	No	Yes	Yes	Yes	Yes	No	Yes	Yes
Dietary saturated fat and cholesterol, and risk of coronary heart disease	No	No	Yes	No	Yes	No	No	Yes
Potassium and the risk of high blood pressure and stroke	No	No	Yes	No	No	No	No	No

*Eligibility based on nutrient values in USDA National Nutrient Database for Standard Reference, Release 23. Nutrient Data Laboratory Home Page, <http://www.ars.usda.gov/nutrientdata>. Individual products may vary based on independent lab analysis. This list is for illustration purposes only. Note: Consult the Code of Federal Regulations for specific nutrition labeling requirements for making health claims.
 **Whole milk, whole milk yogurts, and whole milk and 2% milk fat cottage cheese do not qualify for health claims as they exceed the levels of the disqualifying nutrients specified by the claim and, hence, are not included. (See subsequent pages for disqualifying nutrient levels for specific health claims).

■ ■ ■ Specific Requirements for Individual Health Claims

The FDA provides model claim statements for each of its health claims authorized by regulation. Manufacturers are not required to use the exact language of the model claims in the FDA regulation, but the claim must address all the information provided in the model claim. For more information, go to the FDA website: <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/default.htm>.

Health claims authorized by FDAMA claim notifications and qualified health claims must use the exact claim language specified in the FDAMA claim notification or qualified health claim approval letter.

Specific food and message requirements for individual health claims are shown on pages 23-26.

■ Model Statements for Health Claims for Dairy Products

■ Calcium, vitamin D and osteoporosis

“Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.” or “Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.”

■ Sodium and hypertension

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

■ Dietary fat and cancer

“Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.”

■ Dietary saturated fat and cholesterol, and risk of coronary heart disease

“While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.”

■ Potassium and the risk of high blood pressure and stroke

“Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”

NOTE: Exact claim language must be used.

■ Product and Message Criteria for Individual Health Claims

Calcium, Vitamin D and Osteoporosis [21 CFR 101.72]

Product Criteria

- “High in calcium” (at least 20% of the DV for calcium [200 mg] per reference amount).
- “High in vitamin D” (at least 20% of the DV for vitamin D [80 IU] per reference amount).
- Phosphorus content equal to or less than the calcium content.
- Contains a form of calcium that can be readily absorbed by the body.
- Does not exceed any of the “disqualifying levels” for fat, saturated fat, cholesterol or sodium per reference amount and per serving (total fat: 13 grams; saturated fat: 4 grams; cholesterol: 60 milligrams; sodium: 480 milligrams). If the reference amount is 30 g or less, or 2 tbsp or less, foods must not exceed the “disqualifying levels” per 50 g.
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

Message Criteria

- The claim makes clear the importance of adequate calcium intake or, when appropriate, adequate calcium and vitamin D intake throughout life, in a healthful diet, which are essential to reduce osteoporosis risk.
- The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake or, when appropriate, an adequate dietary calcium and vitamin D intake throughout life.
- The claim may make reference to physical activity.
- The phrase “build and maintain good bone health” may be used to convey the concept of optimizing peak bone mass.

The claim can also be made regarding calcium only and osteoporosis for products that contain more than 200 mg calcium per reference amount, but do not contain adequate vitamin D for the claim.

Sodium and Hypertension [21 CFR 101.74]

Product Criteria

- Must meet the definition for “low sodium” (maximum of 140 mg sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must not exceed the disqualifying levels for fat, saturated fat or cholesterol per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less.
- Must provide at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

Message Criteria

- Claim must state that diets low in sodium “may” or “might” reduce the risk of high blood pressure.
- Claim must specify the nutrient “sodium” and must include the term “high blood pressure.”
- Claim must not quantify the degree of reduction in risk of high blood pressure.
- Claim must indicate that development of high blood pressure depends on many factors.

Dietary Fat and Cancer [21 CFR 101.73]

Product Criteria

- Must meet the definition for “low fat” (maximum of 3 g of total fat per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Does not exceed the disqualifying levels for saturated fat, cholesterol or sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less.
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

Message Criteria

- Claim must state that diets low in fat “may” or “might” reduce the risk of some cancers.
- Claim must use the terms “some types of cancer” or “some cancers” in specifying the disease.
- Claim must use the terms “total fat” or “fat” when specifying the total fat component of the food.
- Claim cannot specify the types of fats or fatty acids that may be related to risk of cancer.
- Claim must not quantify the degree of cancer risk reduction.
- Claim must state that the development of cancer depends on many factors.

Dietary Saturated Fat and Cholesterol, and Risk of Coronary Heart Disease [21 CFR 101.75]**Product Criteria**

- Must meet the definition for “low saturated fat” (maximum of 1 g of saturated fat per reference amount and not more than 15% of the calories from saturated fat).
- Must meet the definition for “low cholesterol” (maximum of 20 mg of cholesterol per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must meet the definition for “low fat” (maximum of 3 g of total fat per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Does not exceed the disqualifying level for sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less.
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

Message Criteria

- Claim must state that diets low in saturated fat and cholesterol “may” or “might” reduce the risk of heart disease.
- In specifying the nutrient, the claim uses the terms “saturated fat” and “cholesterol” and lists both.
- The claim must use the terms “coronary heart disease” or “heart disease” when specifying the disease.
- The claim must not quantify the degree of risk reduction for coronary heart disease.
- The claim must state that the risk of coronary heart disease depends on many factors.

For more information, go to the FDA website: <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/HealthClaimsMeetingSignificantScientificAgreementSSA/default.htm>.

■■■ Health Claim Based on Authoritative Statement

The Food and Drug Administration Modernization Act of 1997 (FDAMA) permits food companies to use a health claim or nutrient content claim in food labeling based on an authoritative health statement from a U.S. government scientific body or a federally approved organization. Examples of federal scientific organizations include the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) or the National Academy of Sciences (NAS).

The FDAMA claim, called an “authoritative statement” claim, can be a health claim about the relationship between a nutrient and a disease or health-related condition, or it can be a nutrient content claim. The health claim must be accurate, subject to “significant scientific agreement,” meet all other existing FDA requirements for health claims, and meet any specific criteria included in the claim notification.

A FDAMA claim may be used on food labels beginning 120 days after the FDA receives a notification of the claim. FDA will inform the submitter by letter as soon as possible within the 120 days when the

notification does not comply with the requirements for a FDAMA notification. When a notification does not meet the requirements the use of the claim is not authorized under FDAMA.

For information on the requirements for FDAMA claims and how to make use of authoritative statement-based health claims, go to: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/UCM056975>.

■ **Product and Message Criteria for Health Claims Based on Authoritative Statements** *Potassium and the Risk of High Blood Pressure and Stroke*

Product Criteria

- Must be a good source of potassium (at least 10% of the DV [350 mg] per reference amount).
- Must meet the definition for “low sodium” (maximum of 140 mg sodium per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must meet the definition for “low fat” (maximum of 3 g of total fat per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Must meet the definition for “low saturated fat” (maximum of 1 g of saturated fat per reference amount and not more than 15% of the calories from saturated fat).
- Must meet the definition for “low cholesterol” (maximum of 20 mg of cholesterol per reference amount and per 50 g if the food’s reference amount is 30 g or less, or 2 tbsp or less).
- Provides at least 10% of the DV for one or more of the following nutrients: vitamin A, vitamin C, iron, calcium, protein or dietary fiber per reference amount prior to any nutrient addition.

Message Criteria

- As a FDAMA authoritative statement-based claim, the exact wording provided in the notification must be used. Required wording for the claim is: “Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.”

■ ■ ■ **Qualified Health Claims**

In 2003, the FDA launched the Consumer Health Information for Better Nutrition Initiative, which provides for the use of qualified health claims when there is emerging evidence for a relationship between a food, food component or dietary supplement and reduced risk of a disease or health-related condition. In these cases, the evidence is not well enough established to meet the significant scientific agreement standard required for the FDA to issue an Authorized Health Claim.

Qualifying language is included as part of the claim statement to explain how the evidence supporting the claim is incomplete. Both conventional foods and dietary supplements may use qualified health claims. The FDA uses its enforcement discretion for qualified health claims after evaluating and ranking the quality and strength of the totality of the scientific evidence. Although the FDA’s “enforcement discretion” letters are issued to the petitioner requesting the qualified health claim, the qualified claims are available for use on any food or dietary supplement product meeting the enforcement discretion conditions specified in the letter. The FDA has prepared a guide on interim procedures for qualified health claims and on the ranking of the strength of evidence supporting a qualified claim. See <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm053832.htm>.

A summary of the qualified health claims authorized by the FDA may be found at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm073992.htm>.

For industry guidance on the FDA’s review system for scientific evaluation of health claims, go to <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm073332.htm>.

STRUCTURE/FUNCTION CLAIMS

Overview/Definitions

Structure/function claims are label statements that describe an effect of a nutrient on the structure or functions of the human body (e.g., calcium builds strong bones) or in affecting general well-being and may be used on food labels and dietary supplement labels. The structure/function claim category does not include claims about effects related to a disease or other health-related condition. Structure/function claims are not subject to any FDA review or approval but must be truthful and not misleading.

When structure/function claims are used on dietary supplement labels, they must be accompanied by the following statement: “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” Dietary supplement manufacturers must also notify the FDA of the structure/function claims they make. Neither the disclaimer statement nor the notification requirement apply to conventional food labels with structure/function claims.

The FDA refers to label statements that describe effects related to a disease or other health-related condition as “disease claims.” The use of disease claims (other than authorized health claims) on a food label can result in the product being subject to drug regulations. Differentiating structure/function claims from disease claims is not always clear-cut. A label statement can be a disease statement based on either the explicit or implied meanings of the claim. For example, a statement that refers to characteristic signs or symptoms of a disease may infer that the intended use of the product is to treat or prevent that disease. In addition to the actual wording of a claim, the context of a claim when viewed with all information on the label will determine if the statement is a disease claim.

The FDA provides industry guidelines to help manufacturers understand the FDA’s thinking on how to distinguish between structure/function claims and disease claims. Although the FDA guideline focuses on dietary supplement claims, the guideline also applies to structure/function claims made for conventional foods.

Structure/Function, Disease and Authorized Health Claims

EXAMPLE WORDING FOR STRUCTURE/FUNCTION CLAIMS DISEASE CLAIMS AND AUTHORIZED HEALTH CLAIMS		
Structure/Function Claim	Disease Claim (unauthorized)	Authorized Health Claim*
Calcium helps build strong bones	Calcium may prevent osteoporosis	Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.
Potassium helps maintain normal blood pressure	Potassium can reduce blood pressure Potassium helps prevent hypertension	Diets containing foods that are a good source of potassium and that are low in sodium may reduce the risk of high blood pressure and stroke.
Vitamin A helps maintain normal vision	Vitamin A helps prevent macular degeneration	None

*See “Health Claim” section

■ ■ ■ Substantiation

Structure/function claims must be substantiated as truthful and not misleading. The FDA provides guidance that explains the FDA “credible and reliable” standard for scientific substantiation of structure/function claims. Although this guideline was prepared for the dietary supplement industry the advice is equally relevant to the substantiation of structure/function claims for conventional foods. Claims made for effects of a food should be substantiated with evidence that the food is effective in providing the claimed effect in humans.

There is no standard formula for how to substantiate structure/function claims. How many studies and what types of evidence are needed will depend on the nature of the claim and the accepted norms in the relevant research disciplines. For example, claims about the known functions of essential nutrients, when used on the label of foods that are a good source of those nutrients, would likely not require any substantiating evidence beyond what can be found in nutrition textbooks. However, a claim that some nonessential component of a food can boost immunity would require considerable evidence from clinical trials to substantiate the truthfulness of the claim.

Marketers who make claims about health-related benefits should consider how these may be interpreted by the reasonable consumer and should make sure that their claims are backed up by sound scientific evidence. The FTC’s concerns about deceptive advertising have led to actions in recent years against manufacturers for immunity, weight loss and other health-related claims.

The key issues a manufacturer must consider in assessing whether the evidence to substantiate a claim meets the competent and reliable scientific evidence standard include:

■ *The meaning of the claim being made*

When the claim is worded such that there is more than one reasonable interpretation, is there substantiation for each interpretation?

■ *The relationship of the evidence to the claim*

Is the substantiating evidence from the same formulation, serving size, and conditions of use as the labeled food? Has the substantiating evidence clearly identified and measured study endpoints relative to the claim? Was the substance tested in a population similar to that which will be using the food? Does the claim accurately reflect the extent, nature or permanence of the effect achieved in the studies?

■ *The quality of the evidence*

Competent and reliable scientific evidence consists of information derived primarily from human studies. Publication of a study in a peer-reviewed journal gives a level of assurance that qualified experts have reviewed the research and found it to be of sufficient quality and validity to merit publication.

Human research must be conducted in compliance with the U.S. requirements for institutional review found in 21 CFR 56. This includes the requirements that the study protocol be approved by an Institutional Review Board (IRB) and the IRB monitor the study to ensure the safety of human subjects.

■ *The totality of the evidence*

Determining if a claim is substantiated requires considering all relevant evidence, both favorable and unfavorable. This means that the substantiation of a claim takes into account more than simply the results from a single study.

■ ■ ■ Examples of Structure/Function Claims for Dairy Products

Milk and other dairy products contain many essential nutrients that support various known, scientifically substantiated physiological functions. Some of the known nutrient/physiological function relationships that are potential structure/function claim topics for dairy products are:

- Vitamin A and the maintenance of normal vision
- Vitamin B₁₂ and maintenance of red blood cells
- Calcium, phosphorus and vitamin D and building strong bones
- Potassium and maintenance of normal blood circulation
- Phosphorus and riboflavin and maintenance of energy metabolism
- Protein and maintenance of muscle tissue

While regulations do not prohibit the use of structure/function claims on foods that exceed the nutrient disclosure levels for fat, saturated fat, cholesterol and sodium, it is advisable to adhere to these values and disclose if they exceed 13 g of fat, 4 g of saturated fat, 60 mg of cholesterol or 480 mg of sodium per reference amount and per 50 g if the reference amount is 30 g or less.

Useful Resources For More Information On Use Of Structure/Function Claims

FDA Regulation for structure/function claims on dietary supplement labels. 21 CFR 101.93 (Note: the 30-day notification and disclaimer statement provisions in this regulation are applicable to dietary supplements only. However, the section clarifying what are disease claims (§101.93(g)) is relevant to conventional food claims).

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?fr=101.93>

FDA Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide. January 2002.

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340.htm>

FDA Guidance for Industry: Substantiation for Dietary Supplement Claims Made under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act. December 2008.

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm073200.htm>

OTHER CLAIMS

Several claims or terms used on food labels and in labeling that are not nutrition-related claims also have been addressed by the FDA and/or other federal agencies, including the FTC and USDA. These include terms, such as those described below, that refer to the production and/or processing of the product.

■ ■ ■ Natural

The FDA has not defined the term “natural” in its food labeling regulations; however, it is the FDA’s long-established policy that “natural” means that nothing artificial or synthetic (including color regardless of source) has been included in or has been added to a product that would not normally be expected to be in the food. Some examples of the FDA “natural policy”:

- Yogurt with added beet juice color is not “natural” since it (1) has added color, and (2) beet juice is not normally expected to be present in yogurt.
- Milk with added vitamin D is not “natural” because the vitamin D₃ added to milk is not “natural.”

The FDA evaluates the use of this term on a case-by-case basis and all claims must be truthful and not misleading.

The USDA also has a policy on the use of “natural” in labeling of meat, poultry and egg products. This policy is similar to the FDA’s, but goes further by requiring that a “natural” product may not contain any chemical preservatives nor may the product or its ingredients be more than minimally processed (USDA FSIS Food Standards and Labeling Policy Book, <http://www.fsis.usda.gov/OPPDE/larc/Policies/PolicyBook.pdf>). As a rule of thumb, “minimal processing” means nothing more than what your grandmother would have done in her kitchen.

■ ■ ■ Fresh

The FDA has defined the terms “fresh,” “fresh frozen” and “frozen fresh” (21 CFR 101.95). The term “fresh” means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation. There are a few ingredient or food treatments that do not preclude the product from using the term “fresh,” including:

- Addition of approved waxes or coatings
- Post-harvest use of approved pesticides
- Application of a mild chloride wash or mild acid wash on produce
- Treatment of raw foods with ionizing radiation not to exceed the maximum dose of one kiloGray in accordance with 21 CFR 179.26
- Refrigeration

The term “fresh” can be used to describe pasteurized milk. Uses of the term “fresh” are not subject to the requirements specified in the regulation if the term does not suggest or imply that a food is unprocessed or unpreserved. The term “fresh” to describe pasteurized milk is not subject to this regulation because consumers commonly understand that milk sold at retail is pasteurized. However, the term “fresh” to describe juice that has been pasteurized or that contains pasteurized juice would be subject to the definition of “fresh” and could not use this term on the label or in labeling.

The terms “fresh frozen” and “frozen fresh” mean that the food was “quickly frozen” while still fresh (i.e., the food had been recently harvested when frozen). “Quickly frozen” means frozen by a freezing system such as blast-freezing (subzero Fahrenheit temperature with fast-moving air directed at the food) that ensures the food is frozen evenly and quickly and with virtually no deterioration to the product. Blanching of the food before freezing does not preclude the product from bearing the term “fresh frozen” or “frozen fresh.”

Organic

In accordance with the Organic Foods Production Act, the USDA has developed regulations regarding organic food production and labeling. The Agricultural Marketing Service of the USDA oversees the National Organic Program (NOP). When a food label uses the term “organic” both production of the agricultural ingredients and the processing of the food product must meet the NOP definition of “organic” and be certified organic by a USDA-licensed certifying body (<http://www.ams.usda.gov/nop/indexIE.htm>).

To qualify for organic labeling, dairy products must be made of milk from cows raised under organic livestock standards as defined in the NOP for at least a year. These standards require that animals have access to outdoor pasture and prohibit the use of growth hormones and prophylactic antibiotics, but allow vaccines and treatment for sick animals (7 CFR 205.238 and 239).

The NOP includes four types of “organic” labeling standards based on the percentage of organic ingredients in food.

NATIONAL ORGANIC PROGRAM LABELING CLAIMS				
	% Organic Ingredients ^a	Required Labeling Statements ^b	Allowable Labeling Statements ^c	Use of Certifying Agent Seal or USDA Organic Seal ^d
“100% Organic”	100%	- Identification of the Certifying Agent	“100% Organic”	Yes
“Organic”	At least 95%	- Identification of the Certifying Agent - Identification of organic ingredients	“Organic” “__% Organic” “__% Organic ingredients”	Yes
“Made with Organic Ingredients”	At least 70%	- Identification of the Certifying Agent - Identification of organic ingredients	“Made with organic ____” “__% Organic” “__% Organic ingredients”	No
“Contains Organic ____” (insert ingredient)	Can contain less than 70%	No organic claims permitted on PDP No required labeling statements	- Organic ingredients may be identified in the ingredient list - A “% Organic” claim may be made on the Information Panel only	No

^aIngredients in the product, except added water and salt, must be organically produced. Products that are not 100% organic (e.g., 95% organic) may contain nonorganic ingredients that are not available in organic form and other substances such as dairy cultures, natural flavors and natural colors (7 CFR 205.605); however, the nonorganic ingredient must be listed in the National List of Allowed and Prohibited Substances (<http://www.ams.usda.gov/nop/NationalList/ListHome.html>).

^bThere are requirements for the placement of organic statements and logos on the package label (7 CFR 205).

^c“100% Organic” and “Organic” can be used in conjunction with the product name. Ingredients may be declared organic in the ingredient statement. However, if a % organic claim is made, the organic ingredients must be identified in the ingredient statement, either by using “organic” in conjunction with the name of the ingredient, or by following organic ingredients with an asterisk or other reference mark which refers to a footnote following the ingredient statement. Other than these statements the label must not make any other reference to organic contents.

^dThe USDA Organic seal is available for download at www.ams.usda.gov/nop/Consumers/Seal.html.

■ ■ ■ Recombinant Bovine Somatotropin (rbST)

In 1993, the FDA approved the use of recombinant bovine somatotropin (rbST) or a recombinant bovine growth hormone (rbGH) for lactating dairy cows to increase the production of marketable milk. The FDA determined after a thorough review that rbST is safe and effective for dairy cows, that milk from cows treated with rbST is safe for human consumption and use of the product does not have a significant impact on the environment.

rbST claims must be truthful, not misleading and should comply with FDA guidance. The FDA has issued guidance regarding rbST labeling, stating that a specific label statement be used on products bearing a rbST claim: *“From cows not treated with rbST. No significant difference has been shown between milk derived from rbST-treated and non-rbST treated cows.”* Other label statements can also meet the FDA’s requirement of providing adequate context, such as an overall explanation of organic milk and how it’s produced.

Statements regarding rbST cannot allow a consumer to conclude that milk from untreated cows is safer or of higher quality than other milk. Labels should not use statements such as “hormone-free” or “rbST-free.” The FDA considers these false and misleading since all milk naturally contains hormones (including bovine somatotropin; bST) and no milk is therefore “bST-free.” Also, an “rbST-free” claim may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk was produced. Instead, “from cows not treated with rbST” or similar statements can be used. All claims must be substantiated with documentation on file that all statements are truthful.

Dairy foods from cows treated with rbST are considered bioengineered foods. The FDA’s guideline for use of labeling statements about bioengineering of food can be found at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm>.

■ ■ ■ Local

The FDA has not defined the term “local” and there is no generally accepted definition for “local” food. However, some states have regulations for the use of this or related claims, but those that exist vary in terms of their requirements. For example, there is not a standard acceptable distance between production and sale. Some allowed claims pertain to foods produced within the state, such as “island fresh” for foods produced in Hawaii. It is important to consider all components of the food, including all ingredients in the food product (e.g., preservatives, flavorings, sweeteners, vitamins, minerals, etc.). All “local” type of claims should be truthful and supportable and in compliance with any state or local regulations, as applicable.

REGULATORY CONCEPTS AND DEFINITIONS FOR DAIRY

■ Nutrient Fortification: General and Dairy-specific

Fortification means adding nutrients to conventional foods, including beverages, and is synonymous with enrichment. Long-established FDA policy has been that there will be no mandatory nutrient fortification of food in the U.S., nor will fortification be prohibited if there is a documented public health need. There are restrictions on maximum use levels for some nutrients included in food additive regulations based on safety, and the levels of optional nutrient fortification of standardized foods (e.g., milk) are specified in their food standards regulations. Even where specifically defined for an enriched standardized food, fortification is voluntary and discretionary. In 1977, the FDA adopted a Fortification Policy to establish a uniform set of principles for the rational addition of nutrients to foods [21 CFR 104.20]. The guideline discourages random fortification of foods, noting that this could result in nutrient imbalances in the food supply. The guideline covers, in part, the addition of nutrients to correct dietary insufficiencies when sufficient information to identify the nutritional problem exists; to restore nutrients lost during storage, handling or processing when normal storage and handling processes cannot prevent the nutrient losses; and to balance the nutrient content of a food under certain specified conditions.

■ Nutrient Fortification of Milk and Milk Products

■ Vitamin A

Many standards of identity specify a required minimum level of vitamin A that must be present if vitamin A is added to a standardized food.

■ Milk

The addition of vitamin A (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) is mandatory in lower-fat milk and milk products (except yogurt) to achieve nutritional equivalency with their full-fat counterparts [21 CFR 130.10(b)]. If vitamin A is added to milk, it must be added at a level to achieve a minimum of 2000 IU of vitamin A per quart thereof within the limits of good manufacturing practice [21 CFR 131.110 (b)(1)]. The acceptable range for vitamin A is 2000-3000 IU per quart (PMO 2007).

■ Cheese

Vitamin A (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) may be added to cheese within current good manufacturing practice conditions of use [21 CFR 184.1930]. Lower-fat cheese products such as reduced-fat and low-fat cheeses must be fortified with vitamin A to achieve nutritional equivalency with their full fat counterparts [21 CFR 130.10(b)].

■ Yogurt

The addition of vitamin A to yogurt is optional. If added, the minimum amount of vitamin A in each 946 milliliters (quart) of the food must not be less than 2000 IU, within the limits of current good manufacturing practice [21 CFR 131.200, 131.203, 131.206]. Unlike the situation for low-fat milk and fat-free milk, low-fat yogurt and fat-free yogurt are not required to be fortified with vitamin A.

■ Vitamin D

The addition of vitamin D (vitamin D₂ or D₃ in crystalline, resin or crystal form) to all milk and milk products is optional and may be added within the limits of good manufacturing practice [21 CFR 184.1950]. Many standards of identity prescribe the minimum level of vitamin D that must be present if it is added to a product. If the standard of identity does not indicate a specified level or the product does not have a standard of identity, then the amount of vitamin D that may be added must be in accordance with [21 CFR 184.1950 or 172.379 and 172.380].

■ Milk

If vitamin D is added to milk, the amount added must achieve a minimum of 400 IU of vitamin D per quart within the limits of good manufacturing practice [21 CFR 131.110 (b)(2)]. The acceptable range for vitamin D is 400-600 IU per quart of milk (PMO 2007).

■ **Cheese**

Vitamin D (vitamin D₂ or D₃ in crystalline or resin form) may be added to cheese, at a level of 89 IU/100 grams [21 CFR 184.1950]. In 2005, the FDA authorized the use of vitamin D₃ at levels up to 81 IU/30 g in cheese and cheese products that have a reference amount of 30 grams [21 CFR 172.380]. This level is slightly more than 20% of the DV. Excluded from this rule are cottage cheese, ricotta cheese and hard grating cheeses, such as Parmesan and Romano and those cheeses defined by a standard of identity.

■ **Yogurt**

The addition of vitamin D to yogurt is optional. If added, the minimum amount of vitamin D in each 946 milliliters (quart) of the food must not be less than 400 IU, within the limits of current good manufacturing practice [21 CFR 131.200, 131.203, 131.206].

■ **Protein and Other Vitamins and Minerals**

The addition of protein and other vitamins and minerals to cheese and cheese products is discretionary and falls under the guidelines in the FDA's Fortification Policy [21 CFR 104.20].

■ **Federal Standards of Identity for Dairy Foods**

Food standards are designed to promote fair competition among food manufacturers and to avoid consumer confusion. The federal standards of identity include definitions, process of producing the product, required and optional ingredients, product nomenclature, required and voluntary label declarations, and methods of analysis [21 CFR, Part 130] and [21 CFR 130.3; 130.5].

Since November 20, 1996, all lower-fat versions of fluid milks and cultured products have been subject to the FDA's "general standard," which permits foods to be named by use of a defined nutrient content claim (e.g., "reduced-fat" or "low-fat") and a standardized term (e.g., "milk" or "cottage cheese"). Although fat contents may vary through the use of nutrient content descriptors, other requirements of the standard must be met, unless otherwise exempted.

■ **Standard of Identity Definitions for Dairy Products**

Many dairy products are subject to a standard of identity established by FDA regulations [21 CFR, Parts 131, 133 and 135]. A standard of identity can define a specific product (e.g., Cheddar cheese or milk) [21 CFR 133.113 and 133.110] or it can encompass an entire category of food (e.g., grated cheeses) [21 CFR 133.146]. Because the number of dairy products with standard of identity requirements is too numerous to summarize here, the following table is provided as a resource to the sections in the CFR where the requirements for specific standardized dairy products can be found:

CLASS OF DAIRY PRODUCTS	SECTION IN CFR
Milk and Cream - Includes milk, cream, sour cream, eggnog, half-and-half and yogurt	21 CFR 131 Subpart B (131.110 - 131.206)
Cheeses and Related Cheese Products - Includes a wide variety of cheeses	21 CFR 133 Subpart B (133.102 - 133.196)
Frozen Desserts - Includes ice cream, frozen custard, sherbert and water ices	21 CFR 135 Subpart B (135.110 - 135.160)

■ Compliance with the Standards of Identity

Compliance with the standards of identity is addressed in [21 CFR 130.8]. Products that have a standard of identity are subject to the regulations under the standard as well as all regulations relating to misbranding and adulteration. Briefly, the three conditions under which a food would not conform to the standard of identity are if the product:

- Contains ingredients that are not provided for in the standard
- Does not contain ingredient(s) required by the standard
- Contains an amount of an ingredient or component not within the limitations of the standard

If any of these conditions or any other requirements of the standard of identity are not met, the product may not be labeled as, or purport to be, such a product. Some conditions where a product may not comply with the federal standard of identity but may still use the name of the standardized food include marketing a product under a temporary marketing permit granted by the FDA ([21 CFR 130.17]), marketing a product with a standard of identity and a nutrient content claim ([21 CFR 130.10]; see “Determining a Product Name” section), and marketing a product in a state or area that has been granted an exemption.

■■■ Grade ‘A’ Pasteurized Milk Ordinance

The Grade “A” Pasteurized Milk Ordinance (PMO 2007; <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSMModelDocuments/PasteurizedMilkOrdinance2007/default.htm>) provides additional guidelines for labeling of Grade A milk and milk products, including buttermilk and buttermilk products, whey and whey products, and condensed and dry milk products. Since the PMO has been adopted by most states, it is generally advisable to follow PMO labeling requirements for all Grade A dairy foods.

The PMO requires that all bottles, containers and packages enclosing Grade A milk and milk products be labeled in accordance with the requirements of the Federal Food, Drug and Cosmetic Act, the Nutritional Labeling and Education Act of 1990, and all applicable regulations in the Code of Federal Regulations. In addition, the products must be conspicuously marked with:

- The words “Grade A” on the exterior surface, meaning principal display panel, the secondary information panel or the cap/cover.
- Identity of the milk plant where pasteurized, ultra-pasteurized, aseptically processed, condensed and/or dried.
- The phrase “Keep refrigerated after opening” on aseptically processed milk and milk products.
- When the product is not from cattle’s milk, the common name of the hooved mammal producing the milk or milk products.
- “Reconstituted” or “Recombined” if applicable.
- Additional requirements apply for condensed or dry milk products (PMO 2007, Section 4).

■ ■ ■ Processing, Nutrient and Ingredient Definitions

The following definitions, described here as processing and nutrient or ingredient definitions, are select examples of definitions from the Code of Federal Regulations [21 CFR Parts 130, 131, 133] and/or the latest revision of the Pasteurized Milk Ordinance (PMO 2007) that are relevant to standards of identity.

Processing Definitions

- **Pasteurized**, when used to describe milk and milk products, means that the product has been heated by properly operated equipment to one of the temperatures specified in the regulation [21 CFR 131.3]. The PMO 2007 offers additional time/temperature relationships for the terms “pasteurization,” “pasteurized” and similar terms (PMO 2007, Section 1). Nothing in the definition bars any other pasteurization process that has been recognized by the FDA to be equally effective and that is approved by the regulatory agency. Milk that is in final package form for beverage use must be pasteurized or ultra-pasteurized [21 CFR 131.110(a)]. The label may indicate the milk was “pasteurized” (optional) [21 CFR 131.110(e)(2)(i)].
- **Ultra-pasteurized**, means milk and milk products that have been thermally processed at or above 138°C (288°F) for at least two seconds, either before or after packaging, to produce a product that has an extended shelf-life under refrigerated conditions [21 CFR 131.3(c)]. If milk has been ultra-pasteurized, the label must indicate “ultra-pasteurized.” [21 CFR 131.110(e)(1)(ii)].
- **Aseptic processing and packaging** is the filling of a commercially sterilized, cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms. The product must maintain commercial sterility under normal nonrefrigerated conditions ([21 CFR 131.3] PMO 2007, Sections 1 and 7).
- **Homogenized** means the fat globule size of the milk or milk product has been reduced to such an extent that after 48 hours of storage no visible cream separation occurs. The fat content also must not differ by more than 10% throughout the product. Whole milk is forced through small openings at extremely high pressures to accomplish this process (Heldman, Encyclopedia of Agriculture, Food and Biological Engineering, 2003). Homogenization of milk is optional. The label of homogenized milk may indicate “homogenized.”
- **Reconstituted or recombined milk and/or milk products** are milk or milk products (Milk and Cream [21 CFR 131], Cottage cheese [21 CFR 133.128] and Dry curd cottage cheese [21 CFR 133.129]) that result from reconstituting or recombining milk constituents with potable water when appropriate. The PMO 2007 notes circumstances where state law does not permit the sale of reconstituted or recombined milk and/or milk products (PMO 2007, Section 1).

Nutrient and Ingredient Definitions

- Nutritive sweeteners and nutritive carbohydrate sweeteners.** The federal standards of identity make the distinction between nutritive sweeteners and nutritive carbohydrate sweeteners. Nutritive sweeteners are substances with more than 2% of the caloric value of sucrose per equivalent unit of sweetening capacity [21 CFR 170.3]. Nutritive carbohydrate sweeteners are sweeteners, such as sucrose and corn syrup that provide sweetness through a carbohydrate source. If the standard of identity provides for “nutritive sweeteners,” then any sweetener providing more than 2% of the calories of sucrose per equivalent unit of sweetening capacity may be used. Below is a list of milk and milk product standards of identity that provide for nutritive sweeteners and nutritive carbohydrate sweeteners.

STANDARDS PERMITTING USE OF NUTRITIVE SWEETENERS	STANDARDS PERMITTING USE OF CARBOHYDRATE SWEETENERS
Milk	Acidified milk
Heavy cream	Cultured milk
Light cream	Yogurt
Light whipping cream	Low-fat yogurt
Sour cream	Fat-free yogurt
Acidified sour cream	Eggnog (Eggnog is required by the federal standard of identity to contain a nutritive carbohydrate)
Half-and-half	

- Non-nutritive sweeteners.** Non-nutritive sweeteners (e.g., sucralose) provide less than 2% of the caloric value of the sucrose per-equivalent sweetening capacity. These sweeteners may be used in foods for which the standard allows for “safe and suitable” sweeteners.

For foods with standards of identity that do not allow for non-nutritive sweeteners, other options may be considered. If the addition of a non-nutritive sweetener would allow for the use of a nutrient content claim (e.g., reduced sugar, no sugar added), the [21 CFR 130.10] provides flexibility in ingredients, including the addition of non-nutritive ingredients. If this is the case, the sweetener must be followed in the ingredient statement by an asterisk referring to a footnote that reads “Ingredient not in regular [food].” The other consideration would involve a food name in two parts: “[standardized food] and [non-nutritive sweetener]” (e.g., “low-fat chocolate milk with sucralose”). All other labeling would remain the same.

- Safe and suitable ingredients.** A safe and suitable ingredient is an ingredient that performs an appropriate function in the food in which it is used, is used at a level no higher than necessary to achieve its intended purpose in that food, and is not a food or color additive that is prohibited in foods [21 CFR 130.3(d)].

Determining a Product Name

The label of a packaged food sold at retail must include an appropriate product name, also called a “statement of identity” [21 CFR 101.3]. The FDA requires that product names accurately identify or describe the basic nature of the food or its characterizing properties or ingredients, be as simple and direct as possible, and not mislead or confuse consumers. When there is not a federal standard of identity that designates the name of the product, the common or usual name of the food must be used. In cases where there is no standard of identity or common or usual name, an appropriately descriptive term with or without a fanciful name may be used. This can be simplified into a three-step process of elimination:

- Is the product covered by a standard of identity?
- Is there a common or usual name?
- If there is no common or usual name, a descriptive term with or without a fanciful name may be used.

■ Standard of Identity for a Food

A standard of identity exists for many dairy products [see “Standard of Identity” section]. The standard of identity for individual foods provides a definition of that food and specifies the appropriate product name. For example, “The name of the food is ‘Cheddar cheese’” [21 CFR 133.113]. For some foods, descriptive terms that must or may accompany the name of the food are provided. For example, for “milk,” the standard of identity specifies both the product name and terms that shall or may accompany the name of the food (e.g., “pasteurized”) that may be used on fluid milk products [21 CFR 131.110].

Any food that resembles or claims to be a standardized food must strictly follow the requirements of the standard of identity. In naming any dairy food, therefore, a manufacturer must consider any possible similarities between that food and a standardized food. These include any similarities in appearance, packaging and taste.

A standard of identity can define a specific product (e.g., Cheddar cheese or milk) or it can encompass an entire category of food (e.g., grated cheeses [21 CFR 133.146]).

■ Common or Usual Name

A common or usual name is one that is most commonly used by manufacturers and well-understood by consumers [21 CFR 101.3(b) and 102.5]. A common or usual name must accurately identify or describe, in simple and direct terms, the basic nature of the food or its characterizing properties or ingredients. In addition, a common or usual name must be uniform among all identical or similar products without being confusingly similar to the name of another food. When the common or usual name is not clear, the following should be considered when determining an appropriate common or usual name: examine current industry practice, consumer understanding of the name and the ordinary dictionary definition of the term(s) in the name. Companies have some latitude in selecting an appropriate common or usual name and, at the same time, must avoid false and misleading statements.

Consumer recognition of a product name and industry practice plays significant roles in establishing both common or usual names and fanciful names. Product names tend to evolve into one or both of these categories gradually over time. Thus, it is sometimes difficult to determine whether a product name is considered to be a common or usual name or a fanciful name, and there may be some overlap between these categories.

■ Descriptive Terms and/or Fanciful Names

If both a standard of identity and an identifiable common or usual name are not available, a descriptive term may be used. This may be accompanied by a fanciful name (most commonly used option), or a fanciful name alone (only permitted when the nature of the food is obvious) [21 CFR 101.3(b)(3)].

When a descriptive term is used, it must be both accurate and complete but does not need to restate all the food’s ingredients. It should convey the basic nature of the food to consumers. Examples include “Pasteurized Process American Cheese Product” and “Lactose-free Nondairy Dessert Topping.”

Descriptive names alone may be lengthy and difficult to remember, therefore, a fanciful name may be accompanied by a descriptive term. The descriptive term accompanying a fanciful name, like a descriptive term used alone, should convey the basic nature of the product to the consumer and should be accurate and complete. Examples include: “Garden Jack Cheese, Monterey Jack Cheese with Garden Vegetables” and “Cheeze & Sticks, Pasteurized Process Cheese Dip and Cracker Sticks.”

A fanciful name may be used alone, without a descriptive term, only when the nature of the food is obvious and the fanciful name is commonly used and understood by the consumer.

■ Other Considerations for Product Naming

■ Standardized Name with a Nutrient Content Claim

If there is a name established by regulation (e.g., a standardized food with a standard of identity) that is the name that must be used as the common or usual name. Either a standardized name (e.g., “Cheddar cheese” or “milk”) or a standardized name with a nutrient content claim (e.g., “reduced-fat Cheddar cheese” or “low-fat milk”) is acceptable. When a product is named using a standardized name with a nutrient content claim, there is flexibility in ingredients granted to the product as long as any ingredient not normally allowed in the standardized product is added to the modified product to make the modified product comparable to the original food [21 CFR 130.10 *“Requirements for foods named by use of a nutrient content claim and a standardized term”*]. An example would be the use of thickeners (gums) in reduced-fat milk to provide a mouth feel and appearance similar to whole milk.

This FDA regulation essentially creates a “generic standard” that allows products with a standard of identity to bear an approved nutrient content claim [21 CFR 130.10]. Examples include “reduced-fat,” “light,” “nonfat,” and “fat-free” in conjunction with standardized terms like “milk” or “cottage cheese.” Fat-modified versions of the “generic” standard of identity must meet the requirements of a nutrient content claim as defined by the FDA. These lower-fat products must meet the nutrient content descriptor definitions for total fat content, be nutritionally equivalent to the reference (i.e., “full fat”) standard of identity and meet all other provisions of the reference standard.

A product with a standard of identity and a nutrient content claim is considered a type of “substitute food.” The FDA requires that a substitute food be nutritionally equivalent to the unaltered product of the same standard of identity, less the nutrient for which the claim is being made. Standardized foods modified to make a nutrient content claim may also add “safe and suitable” ingredients, which are not provided in the standard, to “improve texture, add flavor, prevent syneresis, extend shelf-life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food.” However, in the event such ingredients are not permitted under the standard (or not permitted in excess of a certain level), the ingredient(s) must be specifically identified by an asterisk and one of the following statements must follow the entire ingredient statement: “*Ingredient(s) not in regular _____” or “*Ingredient(s) in excess of amount permitted in regular _____” (the blanks are filled in with the name of the traditional standardized food). If appropriate, both statements must be presented. The qualifying statements must appear in the same type size as the ingredient statement.

■ Food Form

When a food is sold in various optional forms (e.g., shredded or cubed cheese; standard or drinkable yogurt), the form of the food must also be stated as part of the product name [21 CFR 101.3(c)] with the type size reasonably related to the name of the food. If the food form is visible through the container or packaging or depicted clearly as a sketch on the label, the form of the food does not need to be disclosed in written form on the label.

■ Imitation Foods

If a food is a substitute for and resembles another food but is nutritionally inferior to that food, the food must be labeled imitation [21 CFR 101.3(e)]. A product is considered nutritionally inferior if it contains a reduction of 2% or more of the Daily Recommended Value (DRV) of protein and potassium and 2% or more of the U.S. Reference Daily Intake (RDI) of any vitamin or mineral.

■ Combination Foods or 'Multifood'

Foods that combine two or more separate foods into one product may follow an industry practice referred to as a "multifood" concept. Examples of product names for combination dairy foods include "cream cheese with vegetables" and "yogurt with fruit."

■ Flavor Declaration with Product Name

The FDA has detailed requirements about how the primary recognizable flavor(s) or characterizing flavor(s) of a food are represented on the label. There are general regulations dealing with flavor declarations on food labels [21 CFR 101.22]. In addition, many dairy food standards of identity contain specific requirements about using flavoring(s) and declaring flavors(s). The regulations spell out when a dairy food is required – and when it is permitted – to make a flavor declaration on its label. In addition, there are rules about how the flavor declaration should be made. Generally, the name of the characterizing flavor(s) must accompany the product name [21 CFR 101.22(i)(1)]. The type size of the flavor designation must be no less than one-half the height of the letters used in the product name. In addition, the flavoring(s) must be declared in the ingredient list.

■■■ Determining an Ingredient Name

There are many locations within FDA regulations where common or usual names of specific ingredients have been specified by regulation, including: [21 CFR 101.4] *Food; designation of ingredients*, the food standards of identity [21 CFR, Parts 130-169], the food additive regulations [21 CFR, Parts 170-189] and the color additive regulations [21 CFR, Parts 70-82]. In those instances where an ingredient is designated by reference under two different names, FDA generally considers the name designated under the standard of identity to take precedence.

The common or usual name of an ingredient must accurately identify or describe in as simple and direct terms as possible, the basic nature of the food (ingredient) or its characterizing properties, and the name must be uniform among all identical or similar products [21 CFR 102.5 *General principles*]. The specific name of an ingredient must be used in the ingredient statement, not a generic name. For example, "sweeteners" is a generic name for the more specific ingredient names such as "high-fructose corn syrup," "sugar" and "maple syrup." Brand names, acronyms and abbreviations are not considered part of the common or usual name of an ingredient and should not appear in the ingredient statement. There are a few situations where FDA regulations permits the use of a generic name (see table below for allowed generic common or usual names relevant to dairy foods). For example, spice, color and flavor are three collective terms that can be used in lieu of a common or usual name for an individual spice, color or flavor ingredients.

Some of the more frequently used ingredients in dairy products and their common or usual names are shown below.

COMMON OR USUAL NAMES FOR TYPICAL INGREDIENTS USED IN DAIRY PRODUCTS	
Ingredient	Common or Usual Name
Skim milk, concentrated skim milk, reconstituted skim milk, and nonfat dry milk ^{ab}	"skim milk" or "nonfat milk"
Milk, concentrated milk, reconstituted milk, and dry whole milk ^{ab}	"milk"
Bacteria cultures ^{abcde}	"cultured ____" (the blank is filled in with the name of the substrate)
Sweetcream buttermilk, concentrated sweetcream buttermilk, reconstituted sweetcream buttermilk and dried sweetcream buttermilk ^b	"buttermilk"
Whey, concentrated whey, reconstituted whey and dried whey ^b	"whey"
Cream, reconstituted cream, dried cream and plastic cream (sometimes known as concentrated milk fat) ^b	"cream"
Butteroil and anhydrous butterfat ^b	"butterfat"
Dried whole eggs, frozen whole eggs and liquid whole eggs ^b	"eggs"
Dried egg whites, frozen egg whites and liquid egg whites ^b	"egg whites"
Dried egg yolks, frozen egg yolks and liquid egg yolks ^b	"egg yolks"
Milk-clotting enzymes ^{ab}	"enzymes"

^a21 CFR 133.129 *Dry curd cottage cheese*

^b21 CFR 101.4 *Food; designation of ingredients*

^c21 CFR 131.160 *Sour cream*

^d21 CFR 131.162 *Acidified sour cream*

^e21 CFR 133.128 *Cottage cheese*

"New" common or usual names may replace chemical or technical words in the ingredient statement by the establishment of the name through common usage and/or the filing of a citizen petition [21 CFR 10.30 *Citizen petition*]. BHA (butylated hydroxy anisole), BHT (butylated hydroxy toluene) and canola oil (low erucic acid rapeseed oil) are examples of less technical and simpler names that have been established as "new" common or usual names and may be used in place of the more technical common or usual name. For the steviol-based sweeteners, there is presently not a common and usual name.

Dairy foods represent an important source of nutrients. This table provides an overview of selected nutrients for a variety of dairy foods, including fluid milk products, frozen desserts and cheese.

OVERVIEW OF DAIRY PRODUCTS: NUTRITIONAL COMPOSITION

	Total Calories	Total Fat	Saturated Fat	Cholesterol	Sodium	Total Carbohydrates	Sugars	Protein	Vitamin A	Vitamin D	Calcium	Potassium	Magnesium	Phosphorus	Riboflavin	Vitamin B ₂
	Kcal	g	g	mg	mg	g	g	g	IU	IU	mg	mg	mg	mg	mg	mcg
Fluid milk products																
Whole white milk ¹	149	7.9	4.6	24	105	11.7	12.3	7.7	395	124	276	322	24	205	0.41	1.10
Reduced-fat white milk (2%) ¹	122	4.8	3.1	20	115	11.7	12.6	8.1	464	120	293	342	27	224	0.45	1.29
Low-fat white milk (1%) ¹	102	2.4	1.5	12	107	12.2	12.7	8.2	478	117	305	366	27	232	0.45	1.15
Fat-free white milk ¹	83	0.2	0.1	5	103	12.2	12.5	8.3	500	115	299	382	27	247	0.45	1.23
Reduced-fat chocolate milk ¹	190	4.8	2.9	20	165	30.3	23.9	7.5	568	122	272	422	35	255	0.46	0.82
Yogurt, plain, low-fat ²	143	3.5	2.3	14	159	16.0	16.0	11.9	116	2	415	531	39	327	0.49	1.27
Yogurt, plain, fat-free ²	127	0.4	0.3	5	175	17.4	17.4	13.0	16	0	452	579	43	356	0.53	1.38
Cottage cheese, low-fat (1%) ³	81	1.2	0.73	5	459	3.1	3.1	14.0	46	0	69	97	6	151	0.19	0.71
Sour cream ⁴	46	4.7	2.8	12	19	0.7	0.0	0.5	195	3	26	34	2	28	0.04	0.07
Frozen Desserts⁵																
Vanilla ice cream (11% fat)	137	7.3	4.5	29	53	15.6	14.0	2.3	278	5	84	131	9	69	0.16	0.26
Vanilla ice cream (16% fat)	266	17.3	11.1	98	65	23.9	22.1	3.8	699	13	125	168	12	112	0.18	0.42
Vanilla light ice cream	137	3.7	2.2	21	56	22.4	16.8	3.6	340	3	122	158	11	78	0.19	0.36
Orange sherbet	107	1.5	0.9	1	34	22.5	18.0	0.8	34	0	40	71	6	30	0.07	0.10
Cheese⁶																
Pasteurized process American cheese	106	8.9	5.6	27	356	0.5	0.1	6.3	268	7	156	48	8	145	0.10	0.20
Blue	100	8.2	5.3	21	395	0.7	0.1	6.1	216	6	150	73	7	110	0.11	0.35
Brick	105	8.4	5.3	27	159	0.8	0.1	6.6	306	6	191	39	7	128	0.10	0.36
Brie	95	7.9	4.9	28	178	0.1	0.1	5.9	168	6	52	43	6	53	0.15	0.47
Camembert	85	6.9	4.3	20	239	0.1	0.1	5.6	232	5	110	53	6	98	0.14	0.37
Cheddar	114	9.4	6.0	30	176	0.4	0.2	7.1	284	7	204	28	8	145	0.11	0.24
Cream cheese	97	9.7	5.5	31	91	1.2	0.9	1.7	381	7	28	39	3	30	0.04	0.07
Edam	101	7.9	5.0	25	274	0.4	0.4	7.1	234	6	207	53	9	152	0.11	0.44
Feta	75	6.0	4.2	25	316	1.2	1.2	4.0	120	5	140	18	5	96	0.24	0.48
Gouda	101	7.8	5.0	32	232	0.6	0.6	7.1	160	6	198	34	8	155	0.10	0.44
Mozzarella, low moisture, part skim	86	5.7	3.1	15	185	1.1	0.2	7.4	172	4	207	27	7	149	0.09	0.65
Muenster	104	8.5	5.4	27	178	0.3	0.3	6.6	287	6	203	38	8	133	0.09	0.42
Neufchatel	72	6.5	3.6	21	95	1.0	0.9	2.6	238	N/A	33	43	3	39	0.04	0.09
Parmesan (grated) ⁷	22	1.4	0.9	4	76	0.2	<0.1	1.9	43	1	55	6	2	36	0.02	0.11
Provolone	100	7.6	4.8	20	248	0.6	0.2	7.3	249	6	214	39	8	141	0.09	0.41
Ricotta, part skim ⁸	86	4.9	3.1	19	78	3.2	0.2	7.1	238	4	169	78	9	113	0.12	0.18
Romano	110	7.6	4.9	29	340	1.0	0.2	9.0	118	6	302	24	12	215	0.11	0.32
Swiss	108	7.9	5.0	26	54	1.5	0.4	7.6	235	6	224	22	11	161	0.08	0.95

Values presented per
¹ 1 cup ² 8 oz (227 g) ³ 4 oz (113 g) ⁴ 2 tbsp (24 g) ⁵ 1/2 cup ⁶ 1 oz (28 g) ⁷ 1 tbsp (5 g) ⁸ 1/4 cup (62 g)

N/A = Not Available Source: USDA National Nutrient Database for Standard Reference, Release 23 (2010). <http://www.ars.usda.gov/nutrientdata>

The nutrient values are provided as examples and should not be used for nutrition labeling.

Acknowledgment/Resources/Contact Information

■ Acknowledgment

Dairy Research Institute™ assumes all rights and responsibility for this publication. We would also like to acknowledge the help and suggestions of the following individuals for the updates to this *Quick-Reference Guide* from the previous (2009) version:

Peter J. Huth, Ph.D.
PJH Nutritional Sciences
Menomonie, WI.

James E. Hoadley, Ph.D.
EAS Consulting Group, LLC
Alexandria, VA.

■ Resources

Innovation Center for U.S. Dairy™/Dairy Research Institute™
www.USDairy.com

Dairy Management Inc.™, Dairy Research, Technologies, Applications and Nutrition
<http://www.innovatewithdairy.com>

Code of Federal Regulations (CFR), Title 21, Parts 100-169
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition Food Labeling and Nutrition home page
<http://www.fda.gov/Food/LabelingNutrition/default.htm>

Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition “*The Food Labeling Guide*”
<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/default.htm>

Federal Trade Commission, Bureau of Consumer Protection
<http://www.ftc.gov/bcp/about.shtm> or <http://business.ftc.gov/>

International Dairy Foods Association (IDFA) Labeling Manuals: Milk, Cheese and Ice Cream
<http://www.idfa.org/>

Grade “A” Pasteurized Milk Ordinance 2007
<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSMModelDocuments/PasteurizedMilkOrdinance2007/default.htm>

U.S. Department of Agriculture, Agricultural Research Service, 2010. USDA National Nutrient Database for Standard Reference, Release 23. Nutrient Data Laboratory nutrient database search page
<http://www.nal.usda.gov/fnic/foodcomp/search/>

■ Questions?

Contact: Dairy Technical Support Line at 1-800-248-8829 or DairyResearchInstitute@USDairy.com

