LAMP

Linking Agricultural Markets to Producers

Packaging and Label Report

May 2004

Acknowledgments

This Report has been prepared by Ms. Susan Hahn for the LAMP Project, under the direction of the Project staff.

L A M P

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Packaging and Labeling Report

May 2004

Rural and Agricultural Incomes with a
Sustainable Environment (RAISE)
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LAMP Packaging & Labeling

Bosnia I Herzegovina
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Scope of Work

The Scope of Work was mutually changed on the first day of the assignment to better mete the needs of LAMP clients. LAMP clients are relatively small manufacturers with limited finances, they are not in a position to influence packaging research or investment at large packaging companies. As such, they are technology-takers, destined to select their packaging from what is readily available in the market. Therefore, it is necessary that they spend their limited packaging monies on packaging alternatives that best meet the need of consumers.

The initial SOW, which emphasized packaging technology, was changed to emphasize the power of packaging to influence consumer perception and increase consumer spending.

Delivery Method

Over 50 companies participated in the LAMP program.

- 24 companies participated in one-on-one technical assistance and site visits,
- 40 plus companies participated in a packaging seminar and participated in a packaging competition,
- 20 plus companies learned to evaluate packaging design and participated in a peer-review.

Potential LAMP Activities to Encourage the Development of Sound Packaging

1. **Problem:** Manufacturers enjoy manufacturing product, not identifying and understanding consumers. In addition, most do not have an independent sales or marketing division to focus energy on understanding the client. Hence, most packaging represents the "creative ideas" of the owner, who is seldom in touch with market trends.

   Answer: Create a Marketing Association (MA). LAMP clients can join for a fee and have the association create a comprehensive marketing strategy that includes a packaging component. The MA would assist members with packaging type, branding, logo creation, color selection, etc. Membership fees would provide the association with revenue to cover costs and generate a profit. The members would have the benefit of a talented marketing group, without having to bear the full costs of an internal department.

2. **Problem:** The dearth of centrally gathered consumer data means that LAMP clients must conduct this research themselves (this may change as bar-code technology increases). LAMP clients are scared to speak to consumers, and will

avoid doing so at all costs. Yet, they need to survey consumers to learn of special packaging opportunities, trends, spend analysis, etc.

Answer: Cooperate with a leading university and select a professor to lead a summer research group of 3rd and 4th year university students. The professor will create the survey and train students to conduct the consumer survey in retail stores. They will work together to consolidate and analyze the information. At the end of the summer, the students will present the information to LAMP participants. The university will offer students credit for the class, and LAMP may offer a student stipend.

3. **Problem:** LAMP clients make isolated packaging decisions, and don't use consumer feedback to improve packaging ideas.

   MA can use the university students' consumer profile to gather "typical users" and create/train a consumer panel. The panel would meet as needed to evaluate packaging ideas prior to launch; so that consumer feedback could be incorporated into packaging design before LAMP clients make final packaging decision. The panel is trained on how to give feedback. In the US, a trained panel member will often make $80/hour, and work for 1-3 hours per month.

4. **Problem:** "This is not the United States. Our clients can't afford nice packaging." It is easy for LAMP clients to dismiss packaging information that challenges their current packaging protocol.

   Answer: Create case studies of companies that have created strong brand identity and consumer packaging. State the major decision points that led to investing money into packaging design, and the monetary results. Two such companies could be Neven (MAP) and Swity (fruit products).

5. **Problem:** LAMP clients find it overwhelming to monitor the packaging industry and identify packaging partners.

   Answer: Hold a packaging trade fair in a central location. Each company could have a both demonstrating its capabilities, and could be allotted a presentation period in which it could educate LAMP clients on market trends, packaging trends, packaging design, etc.

Technical Assistance with Selected Companies

The following table summarizes the top three packaging priorities discussed with each company during technical assistance. In Bihac, packaging was evaluated during the LAMP sponsored MAP Buyer Meeting. All other companies were provided with one-on-one technical assistance at their manufacturing site and/ or retail location.

LAMP clients especially keen to adopt new ideas are Dragon (fruit company associated with the Banja Luka office), Halilovic and Agropodrinje/Agrodina (fruit company associated with the Sarajevo office).

Company	Industry	Action Steps	Location
Halilovic	MAP	• Label burlap bags used for export with company information. • Conduct consumer research, design, and test market new tax-free display canister. • Contact international buyers and ask about packaging performance in warehousing.	Sarajevo
Faveda	MAP	• Must improve or find alternative to poor quality, plastic cosmetic containers. • Start interacting with clients in their own store to determine consumer-driven convenience packaging alternatives. • The bag, in the bag in-box package, must be labeled with company information.	Sarajevo
Vextra	MAP	• Portion packed tea bags should use standard, not specially designed, materials to contain costs. • Any new product launches should be co-packed by an outside manufacturer. The procurement of expensive machinery on market speculation must be avoided. • Label all bulk bags with company information.	Mostar
Roing	Spices	• Leverage Dutch marketing experience. • Create new brand of low-cost, bulk spices to encourage first time buyers to use spices and later to graduate to more expensive product lines. • Convenience pack spice mixes into beef, pork and poultry blends for ease-of-use.	Mostar
AgroPro	MAP	• Include directions for use and contact information in essential oil tourist pack. • Conduct consumer research with potential buyers for innovative product ideas.	Mostar

		• Create company logo that is consistent with desired brand image and use on all products.	
Neven	MAP	• Eliminate duplicate information on multiple side panels. Use side panels for instructions or product line awareness. • Create marketing campaign for interior tea bag. • Consider promotions that reward buyers for purchasing multiple, different products.	Bihac
Biljana (3B)	Packaged Foods	• Create a consistent logo and brand identity. • Place logo in the same location on all packaged goods. • Print consumer directions on packaging.	Bihac
Elmar	Essential Oils	• Eliminate duplicate wording such as "organic" and "100% natural". • Place "Elmar" in position that can be seen by consumer (currently on the side). • Consider revising industrial looking logo for consumer products.	Bihac
Adonis	MAP	• Print instructions on packaging. • Create marketing for white bags and tea bags. • Eliminate duplicate panels and replace with multiple use ideas.	Bihac
Celikovic	MAP	• Create directions for use on brandy products. • Label inside white bag. • Create marketing for white bags.	Bihac
Ljekobilija	MAP	• Create marketing for white bags and tea bags. • Eliminate duplicate panels and replace with multiple use ideas.	Bihac
Vitamark	Dairy	• Use bold colors in logo, place logo and certificate logos in the same place on all packaging. • Consumer usage should be used to resize packaging, and consumer feedback should be used to create convenient packaging. • Eliminate unprofitable lines and expand popular brand demand with seasonal promotions to moderate seasonal variations in supply and price.	Banja Luka
Sunce	MAP	• Emotionally distance the owner from the brand so that the package can be redesigned. • Redesign packaging to correlate with typical customer usage (7 day portions vs. 30 day portions). • Customers say they are willing to pay 10-15%	Banja Luka

		more for good packaging. Take advantage of this and redesign retail packaging.	
Dragon	Vegetables	• Apply for Bar Code. • Use client's preferred packaging supplier to guarantee client satisfaction. Inquire about corner post alternatives. • Create standard, simple, bold logo that can be used on entire line of vegetable boxes and packaging to reduce packaging inventory. • Print on backside of potato label.	Banja Luka
Kap Po Kap	Chestnuts	• Current packaging is cheap and does not protect product from freezer burn. Change to plastic bag in box for added protection and display appeal. • Directions for use (thaw time) must be printed on labels. • Hire short-term packaging manager to research packaging alternatives and to sell product into retail outlets.	Banja Luka

Inmer	Milk Products	• Update Tetra Pak to include easy to pour spout • Consistent placement of logo on package • Use solid, bold colors	Tuzla
Anna	Cheese	• Use opaque plastic (versus clear) to hide unattractive aspects of cheese product. • Understand full use of bar coding, and eliminate the need for two conflicting codes on each package. • Center the label onto the cheese product.	Tuzla
Swifty	Juices, Jams	• At future point can use a better, complimentary color on juice products, that won't wash out color of juice products (green, blue) • Can optimize back panel and create consumer message. • Very Strong packaging in general.	Tuzla
Apropodrinje and Agrodrina	Apples	• Create new logo that represents: healthy, quality, tradition and reputation. We discussed many options. • Draft logo and test with consumers for feedback. • Use crisp colors and create a clear logo that can be reproduced well by the manufacturer.	Sarajevo
Travnik Cooperative, Gesufarms,	Milk and cheese products	• Understand the role of consumers in packaging decisions • Create packaging that meets consumers' needs	Sarajevo

Vslasic Milk		of convenience and use. • Ensure that the cost of the package is incorporated into the price of the product.	
Kvas	Packaged Food Company	• Strengthen Brand Image by emphasizing the KVAS logo on packaging. • Define the end consumer and make packaging convenient to drive finished product value. • Color usage: contrasting bold colors should be used to compliment the packaged product (eg. avoid deep purple/black packaging with plums.)	Sarajevo

Hand-out Materials

1. How to Evaluate Your Packaging Materials

How to evaluate one's own packaging was explained to all LAMP clients. The following handouts should be reviewed with participants frequently, since many struggled to evaluate the components separately, which prohibits an objective evaluation.

Note: All four packaging types can and should be evaluated. Ensure that LAMP clients do not mix the type of packaging that they are evaluating. (Eg. A milk bottle in a corrugated box should be evaluated twice, as both a primary and a secondary package.) This is a common mistake.

Purpose of Packaging

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- Containment
  - Divide bulk products into consumer sized quantities
- Protection
  - Preserve product integrity
- Convenience
  - Consumer
  - Distribution
- Communication
  - "A package must protect what is sells and sell what it protects"
  - Your "Silent Salesman"

Packaging Failure

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Comes from ignoring these three environments:

Physical Environment: Environment where damage may occur

shocks (drops,bumps); vibration (rail/sea); compression (stacking)

Ambient Environment: The environment surrounding the package

humidity, light, dust, exhaust fumes, water vapor…

Human Environment: Environment of Consumer Interaction

limitations of human strength, vision, usage, typical portion, ability to hold…

Evaluating Packaging Performance

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Environment

Function

	Physical	Ambient	Human
Containment			
Protection			
Convenience			
Communication			

Food Packaging, Principles and Practice, Gordon, L. Robertson

1. Packaging Design Flow Charts

"A model for teaching packaging development at undergraduate level", by Jorge Marcondes and Ron Thomas, provides us with two wonderful diagrams that can be shared with LAMP clients when they decide to redesign current packaging, or design packaging for a new product.

The first diagram visually demonstrated that the development of product and packaging occurs concurrently. This is important for LAMP clients, as most complete product development before considering packaging development. The key is, that most of the LAMP clients spend a significant portion of their development resources (money) on product development, leaving little if anything for packaging.

Secondly, the diagram demonstrates that one spends money during the development phase and then makes money via profit after both the product and packaging are fully designed and completed. To complete half of this phase simply draws out the timeline and delays the period of profitability.

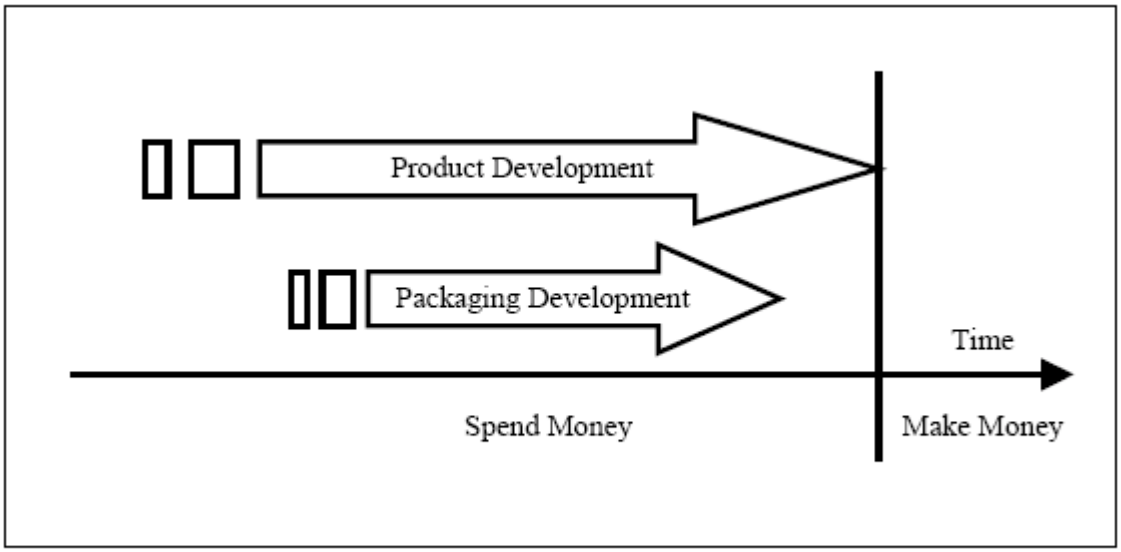
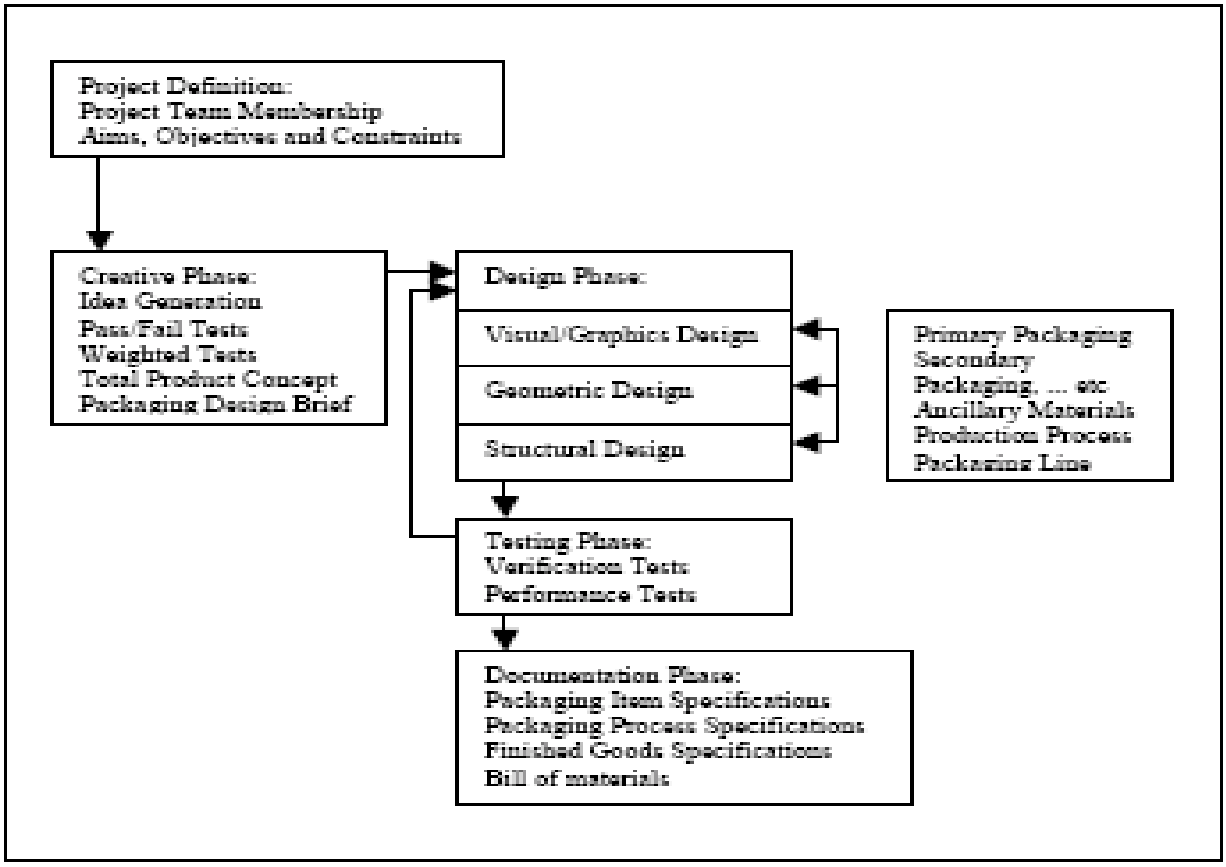


Figure 1. Concurrent product and packaging development

3. Packaging Flow Charts

Diagram two outlines a typical packaging design flow chart, as used by most food companies in the United States. LAMP clients may modify this flow chart to meet their needs. However, great care should be taken to emphasis the testing, verification and performance test activities, which are currently ignored by LAMP clients.

Typical Packaging Development Flow Chart



RESOURCES

Articles

- The Food Label
- The Food Labeling Guide
- Relative (or Comparative) Claims
- Nutritional Facts Panel Protocol
- Additional FDA Assistance (Websites)
- Claims: Conventional Foods and Dietary Supplements
- European Union Labeling Regulations (see additional information on diskette)
- Bar Codes, Bosnia Herzegovina
- Bar Code, US
- Packaging Terminology
- Packaging Machines, Definitions
- Illnesses and Injuries Associated With the Use of Selected Dietary Supplements
- FDA Actions on New Bioterrorism Legislation

Books

From Kitchen to Market, Stephen F. Hall (left at Banja Luka office)
Food Packaging, Principles and Practice, Gordon, L. Robertson (left at Sarajevo office)

Packaging Presentation

See Power Point

Useful Internet Sites:

Code of Federal Regulations, Title 21 (CFR Title 21)

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

EU regulations on food and labeling.

Eur-lex website which gives all EU law:
http://europa.eu.int/eur-lex/en/

European Food Safety Authority:
http://www.efsa.eu.int/
which contains the following link for food labeling:
http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/comm_legisl_en.html

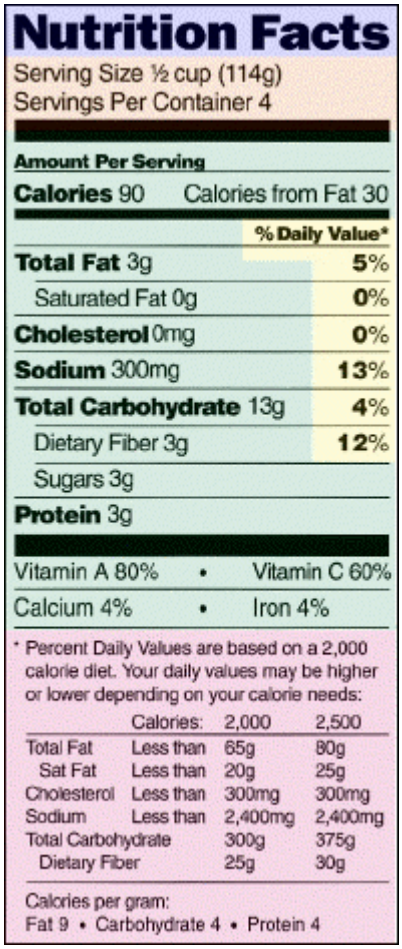
U. S. Department of Health and Human Services
U. S. Food and Drug Administration
FDA Backgrounder
May 1999

July 9, 2003: For updated examples of nutrition labels
see Examples of Revised Nutrition Facts Panel Listing Trans Fat.

The Food Label

Grocery store aisles are avenues to greater nutritional knowledge.

Under regulations from the Food and Drug Administration of the Department of Health and Human Services and the Food Safety and Inspection Service of the U.S. Department of Agriculture, the food label offers more complete, useful and accurate nutrition information than ever before.



Nutrition Facts
Serving Size ½ cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 90	Calories from Fat 30
	% Daily Value*
Total Fat 3g	**5%**
Saturated Fat 0g	**0%**
Cholesterol 0mg	**0%**
Sodium 300mg	**13%**
Total Carbohydrate 13g	**4%**
Dietary Fiber 3g	**12%**
Sugars 3g	
Protein 3g	

Vitamin A 80% • Vitamin C 60%
Calcium 4% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

With today's food labels, consumers get:

- nutrition information about almost every food in the grocery store
- distinctive, easy-to-read formats that enable consumers to more quickly find the information they need to make healthful food choices
- information on the amount per serving of saturated fat, cholesterol, dietary fiber, and other nutrients of major health concern
- nutrient reference values, expressed as % Daily Values, that help consumers see how a food fits into an overall daily diet
- uniform definitions for terms that describe a food's nutrient content--such as "light," "low-fat," and "high-fiber"--to ensure that such terms mean the same for any product on which they appear
- claims about the relationship between a nutrient or food and a disease or health-related condition, such as calcium and osteoporosis, and fat and cancer. These are helpful for people who are concerned about eating foods that may help keep them healthier longer.
- standardized serving sizes that make nutritional comparisons of similar products easier
- declaration of total percentage of juice in juice drinks. This enables consumers to know exactly how much juice is in a product.

Select any part of the food label graphic to find the relevant sections of this document.

NLEA

These and other changes are part of final rules published in the *Federal Register* in 1992 and 1993. FDA's rules implement the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), which, among other things, requires nutrition labeling for most foods (except meat and poultry) and authorizes the use of nutrient content claims and appropriate FDA-approved health claims.

Meat and poultry products regulated by USDA are not covered by NLEA. However, USDA's regulations closely parallel FDA's rules, summarized here.

Nutrition Labeling--Applicable Foods

Under these rules, nutrition labeling is required for most foods. In addition, voluntary nutrition information is available for many raw foods: the 20 most frequently eaten raw fruits, vegetables and fish each, under FDA's voluntary point-of-purchase nutrition information program, and the 45 best-selling cuts of meat, under USDA's program.

Although voluntary, FDA's program for raw produce and fish carries a strong incentive for retailers to participate. The program will remain voluntary only if at least 60 percent of a nationwide sample of retailers continue to provide the necessary information. (In a 1996 survey, FDA found that more than 70 percent of U.S. food stores were complying.)

Also nutrition information is required for some restaurant foods. FDA requires nutrition information for foods about which health or nutrient-content claims are made on restaurant menus, signs or placards. Restaurants have to provide a "reasonable basis" for making claims, although they are given some flexibility in demonstrating that reasonable basis. For example, they could rely on recipes endorsed by medical or dietary groups.

Nutrition Labeling--Exemptions

Under NLEA, some foods are exempt from nutrition labeling. These include:

- food served for immediate consumption, such as that served in hospital cafeterias and airplanes, and that sold by food service vendors--for example, mall cookie counters, sidewalk vendors, and vending machines
- ready-to-eat food that is not for immediate consumption but is prepared primarily on site--for example, bakery, deli, and candy store items
- food shipped in bulk, as long as it is not for sale in that form to consumers
- medical foods, such as those used to address the nutritional needs of patients with certain diseases
- plain coffee and tea, some spices, and other foods that contain no significant amounts of any nutrients.

Food produced by small businesses also may be exempt, under 1993 amendments to the NLEA. Businesses with fewer than 100 full-time equivalent employees may claim an exemption for food products that have U.S. sales of fewer than 100,000 units annually. Companies claiming this

exemption must notify FDA that they meet the criteria before they begin marketing their products. U.S. companies, other than importers, with fewer than 10 full-time equivalent employees and selling fewer than 10,000 units of a food in a year also are exempt but do not need to notify FDA. Also exempt are retailers with annual gross sales in the United States of less than $500,000 or with annual gross sales of food to consumers in the United States of less than $50,000.

Although certain foods may be exempt, they are free to carry nutrition information, when appropriate--as long as it complies with regulations. Also, these foods will lose their exemption if their labels carry a nutrient content or health claim or any other nutrition information.

Nutrition information about game meats--such as deer, bison, rabbit, quail, wild turkey, and ostrich--is not required on individual packages. Instead, it can be given on counter cards, signs, or other point-of-purchase materials. Because few nutrient data exist for these foods, FDA believes that allowing this option will enable game meat producers to give first priority to collecting appropriate data and make it easier for them to update the information as it becomes available.

Nutrition Information Panel

Under the label's "Nutrition Facts" panel, manufacturers are required to provide information on certain nutrients. The mandatory (underlined) and voluntary components and the order in which they must appear are:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
- other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol if declared)
- protein
- vitamin A
- percent of vitamin A present as beta-carotene
- vitamin C
- calcium
- iron
- other essential vitamins and minerals

If a claim is made about any of the optional components, or if a food is fortified or enriched with any of them, nutrition information for these components becomes mandatory.

These mandatory and voluntary components are the only ones allowed on the Nutrition Facts panel. The listing of single amino acids, maltodextrin, calories from polyunsaturated fat, and calories from carbohydrates, for example, may not appear as part of the Nutrition Facts on the label.

The required nutrients were selected because they address today's health concerns. The order in which they must appear reflects the priority of current dietary recommendations.

Nutrition Panel Format

All nutrients must be declared as percentages of the Daily Values which are label reference values. The amount, in grams or milligrams, of macronutrients (such as fat, cholesterol, sodium, carbohydrates, and protein) are still listed to the immediate right of these nutrients. But, for the first time, a column headed "% Daily Value" appears on the far right side.

Declaring nutrients as a percentage of the Daily Values is intended to prevent misinterpretations that arise with quantitative values. For example, a food with 140 milligrams (mg) of sodium could be mistaken for a high-sodium food because 140 is a relatively large number. In actuality, however, that amount represents less than 6 percent of the Daily Value for sodium, which is 2,400 mg.

On the other hand, a food with 5 g of saturated fat could be construed as being low in that nutrient. In fact, that food would provide one-fourth the total Daily Value because 20 g is the Daily Value for saturated fat.

Nutrition Panel Footnote

The % Daily Value listing carries a footnote saying that the percentages are based on a 2,000-calorie diet. Some nutrition labels--at least those on larger packages--have these additional footnotes:

- a sentence noting that a person's individual nutrient goals are based on his or her calorie needs
- lists of the daily values for selected nutrients for a 2,000- and a 2,500-calorie diet.

An optional footnote for packages of any size is the number of calories per gram of fat (9), and carbohydrate and protein (4).

Format Modifications

In some circumstances, variations in the format of the nutrition panel are allowed. Some are mandatory. For example, the labels of foods for children under 2 (except infant formula, which has special labeling rules under the Infant Formula Act of 1980) may not carry information about saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, calories from fat, or calories from saturated fat.

The reason is to prevent parents from wrongly assuming that infants and toddlers should restrict their fat intake, when, in fact, they should not. Fat is important during these years to ensure adequate growth and development.

The labels of foods for children under 4 may not include the % Daily Values for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber. They may carry % Daily Values for protein, vitamins and minerals, however. These nutrients are the only ones for which FDA has set Daily Values for this age group.

Thus, the top portion of the "Nutrition Facts" panels of foods for children under 4 will consist of two columns. The nutrients' names will be listed on the left and their quantitative amounts will be on the right. The bottom portion will provide the % Daily Values for protein, vitamins and minerals. Only the calorie conversion information may be given as a footnote.

Some foods qualify for a simplified label format. This format is allowed when the food contains insignificant amounts of seven or more of the mandatory nutrients and total calories. "Insignificant" means that a declaration of zero could be made in nutrition labeling, or, for total carbohydrate, dietary fiber, and protein, the declaration states "less than 1 g."

For foods for children under 2, the simplified format may be used if the product contains insignificant amounts of six or more of the following: calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron.

If the simplified format is used, information on total calories, total fat, total carbohydrate, protein, and sodium--even if they are present in insignificant amounts--must be listed. Other nutrients, along with calories from fat, must be shown if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too.

Some format exceptions exist for small and medium-size packages. Packages with less than 12 square inches of available labeling space (about the size of a package of chewing gum) do not have to carry nutrition information unless a nutrient content or health claim is made for the product. However, they must provide an address or telephone number for consumers to obtain the required nutrition information.

If manufacturers wish to provide nutrition information on these packages voluntarily, they have several options: (1) present the information in a smaller type size than that required for larger packages, or (2) present the information in a tabular or linear (string) format.

The tabular and linear formats also may be used on packages that have less than 40 square inches available for labeling and insufficient space for the full vertical format.

Other options for packages with less than 40 square inches of label space are:

- abbreviating names of dietary components
- omitting all footnotes, except for the statement that "Percent Daily Values are based on a 2,000-calorie diet"
- placing nutrition information on other panels readily seen by consumers.

A select group of packages with more than 40 square inches of labeling space is allowed a format exception, too. These are packages with insufficient vertical space (about 3 inches) to

accommodate the required information. Some examples are bread bags, pie boxes, and bags of frozen vegetables. On these packages, the "Nutrition Facts" panel may appear, in tabular format, with the footnote information appearing to the far right.

For larger packages in which there is not sufficient space on the principal display panel or the information panel (the panel to the right of the principal display), FDA allows nutrition information to appear on any label panel that is readily seen by consumers. This lessens the chances of overcrowding of information and encourages manufacturers to provide the greatest amount of nutrition information possible.

For products that require additional preparation before eating, such as dry cake mixes and dry pasta dinners, or that are usually eaten with one or more additional foods, such as breakfast cereals with milk, FDA encourages manufacturers to provide voluntarily a second column of nutrition information. This is known as dual declaration.

With this variation, the first column, which is mandatory, contains nutrition information for the food as purchased. The second gives information about the food as prepared and eaten.

Still another variation is the aggregate display. This is allowed on labels of variety-pack food items, such as ready-to-eat cereals and assorted flavors of individual ice cream cups. With this display, the quantitative amount and % Daily Value for each nutrient are listed in separate columns under the name of each food.

Serving Sizes

The serving size remains the basis for reporting each food's nutrient content. However, unlike in the past, when the serving size was up to the discretion of the food manufacturer, serving sizes now are more uniform and reflect the amounts people actually eat. They also must be expressed in both common household and metric measures.

FDA allows as common household measures: the cup, tablespoon, teaspoon, piece, slice, fraction (such as "1/4 pizza"), and common household containers used to package food products (such as a jar or tray). Ounces may be used, but only if a common household unit is not applicable and an appropriate visual unit is given--for example, 1 oz (28g/about 1/2 pickle).

Grams (g) and milliliters (mL) are the metric units that are used in serving size statements.

NLEA defines serving size as the amount of food customarily eaten at one time. The serving sizes that appear on food labels are based on FDA-established lists of "Reference Amounts Customarily Consumed Per Eating Occasion."

These reference amounts, which are part of the regulations, are broken down into 139 FDA-regulated food product categories, including 11 groups of foods specially formulated or processed for infants or children under 4. They list the amounts of food customarily consumed per eating occasion for each category, based primarily on national food consumption surveys. FDA's list also gives the suggested label statement for serving size declaration. For example, the category "breads (excluding sweet quick type), rolls" has a reference amount of 50 g, and the appropriate label statement for sliced bread or roll is "___ piece(s) (_ g)" or, for unsliced bread, "2 oz (56 g/_ inch slice)."

The serving size of products that come in discrete units, such as cookies, candy bars, and sliced products, is the number of whole units that most closely approximates the reference amount. Cookies are an example. Under the "bakery products" category, cookies have a reference amount of 30 g. The household measure closest to that amount is the number of cookies that comes closest to weighing 30 g. Thus, the serving size on the label of a package of cookies in which each cookie weighs 13 g would read "2 cookies (26 g)."

If one unit weighs more than 50 percent but less than 200 percent of the reference amount, the serving size is one unit. For example, the reference amount for bread is 50 g; therefore, the label of a loaf of bread in which each slice weighs more than 25 g would state a serving size of one slice.

Certain rules apply to food products that are packaged and sold individually. If such an individual package is less than 200 percent of the applicable reference amount, the item qualifies as one serving. Thus, a 360-mL (12-fluid-ounce) can of soda is one serving, since the reference amount for carbonated beverages is 240 mL (8 ounces).

However, if the product has a reference amount of 100 g or 100 mL or more and the package contains more than 150 percent but less than 200 percent of the reference amount, manufacturers have the option of deciding whether the product can be one or two servings.

An example is a 15-ounce (420 g) can of soup. The serving size reference amount for soup is 245 g. Therefore, the manufacturer has the option to declare the can of soup as one or two servings.

Daily Values--DRVs

The new label reference value, Daily Value, comprises two sets of dietary standards: Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs). Only the Daily Value term appears on the label, though, to make label reading less confusing.

DRVs have been established for macronutrients that are sources of energy: fat, saturated fat, total carbohydrate (including fiber), and protein; and for cholesterol, sodium and potassium, which do not contribute calories.

DRVs for the energy-producing nutrients are based on the number of calories consumed per day. A daily intake of 2,000 calories has been established as the reference. This level was chosen, in part, because it approximates the caloric requirements for postmenopausal women. This group has the highest risk for excessive intake of calories and fat.

DRVs for the energy-producing nutrients are calculated as follows:

- fat based on 30 percent of calories
- saturated fat based on 10 percent of calories
- carbohydrate based on 60 percent of calories
- protein based on 10 percent of calories. (The DRV for protein applies only to adults and children over 4. RDIs for protein for special groups have been established.)
- fiber based on 11.5 g of fiber per 1,000 calories.

Because of current public health recommendations, DRVs for some nutrients represent the uppermost limit that is considered desirable.The DRVs for total fat, saturated fat, cholesterol, and sodium are:

- total fat: less than 65 g
- saturated fat: less than 20 g
- cholesterol: less than 300 mg
- sodium: less than 2,400 mg

Daily Values--RDIs

"Reference Daily Intake" replaces the term "U.S. RDA," which was introduced in 1973 as a label reference value for vitamins, minerals and protein in voluntary nutrition labeling. The name change was sought because of confusion that existed over "U.S. RDAs," the values determined by FDA and used on food labels, and "RDAs" (Recommended Dietary Allowances), the values determined by the National Academy of Sciences for various population groups and used by FDA to figure the U.S. RDAs.

However, the values for the new RDIs remain the same as the old U.S. RDAs for the time being.

Nutrient Content Claims

The regulations also spell out what terms may be used to describe the level of a nutrient in a food and how they can be used. These are the core terms:

- **Free.** This term means that a product contains no amount of, or only trivial or "physiologically inconsequential" amounts of, one or more of these components: fat, saturated fat, cholesterol, sodium, sugars, and calories. For example, "calorie-free" means fewer than 5 calories per serving, and "sugar-free" and "fat-free" both mean less than 0.5 g per serving. Synonyms for "free" include "without," "no" and "zero." A synonym for fat-free milk is "skim".
- **Low.** This term can be used on foods that can be eaten frequently without exceeding dietary guidelines for one or more of these components: fat, saturated fat, cholesterol, sodium, and calories. Thus, descriptors are defined as follows:
    - **low-fat**: 3 g or less per serving
    - **low-saturated fat**: 1 g or less per serving
    - **low-sodium**: 140 mg or less per serving
    - **very low sodium**: 35 mg or less per serving
    - **low-cholesterol**: 20 mg or less and 2 g or less of saturated fat per serving
    - **low-calorie**: 40 calories or less per serving.

Synonyms for low include "little," "few," "low source of," and "contains a small amount of."

- **Lean and extra lean**. These terms can be used to describe the fat content of meat, poultry, seafood, and game meats.
    - **lean**: less than 10 g fat, 4.5 g or less saturated fat, and less than 95 mg cholesterol per serving and per 100 g.
    - **extra lean**: less than 5 g fat, less than 2 g saturated fat, and less than 95 mg cholesterol per serving and per 100 g.

- **High**. This term can be used if the food contains 20 percent or more of the Daily Value for a particular nutrient in a serving.
- **Good source**. This term means that one serving of a food contains 10 to 19 percent of the Daily Value for a particular nutrient.
- **Reduced**. This term means that a nutritionally altered product contains at least 25 percent less of a nutrient or of calories than the regular, or reference, product. However, a reduced claim can't be made on a product if its reference food already meets the requirement for a "low" claim.
- **Less**. This term means that a food, whether altered or not, contains 25 percent less of a nutrient or of calories than the reference food. For example, pretzels that have 25 percent less fat than potato chips could carry a "less" claim. "Fewer" is an acceptable synonym.
- **Light**. This descriptor can mean two things:
    - First, that a nutritionally altered product contains one-third fewer calories or half the fat of the reference food. If the food derives 50 percent or more of its calories from fat, the reduction must be 50 percent of the fat.
    - Second, that the sodium content of a low-calorie, low-fat food has been reduced by 50 percent. In addition, "light in sodium" may be used on food in which the sodium content has been reduced by at least 50 percent.

  The term "light" still can be used to describe such properties as texture and color, as long as the label explains the intent--for example, "light brown sugar" and "light and fluffy."

- **More**. This term means that a serving of food, whether altered or not, contains a nutrient that is at least 10 percent of the Daily Value more than the reference food. The 10 percent of Daily Value also applies to "fortified," "enriched" and "added" "extra and plus" claims, but in those cases, the food must be altered.

Alternative spelling of these descriptive terms and their synonyms is allowed--for example, "hi" and "lo"--as long as the alternatives are not misleading.

Healthy. A "healthy" food must be low in fat and saturated fat and contain limited amounts of cholesterol and sodium. In addition, if it' s a single-item food, it must provide at least 10 percent of one or more of vitamins A or C, iron, calcium, protein, or fiber. Exempt from this "10-percent" rule are certain raw, canned and frozen fruits and vegetables and certain cereal-grain products. These foods can be labeled "healthy," if they do not contain ingredients that change the nutritional profile, and, in the case of enriched grain products, conform to standards of identity, which call for certain required ingredients. If it's a meal-type product, such as frozen entrees and multi-course frozen dinners, it must provide 10 percent of two or three of these vitamins or minerals or of protein or fiber, in addition to meeting the other criteria. The sodium content cannot exceed 360 mg per serving for individual foods and 480 mg per serving for meal-type products.

Other Definitions

The regulations also address other claims. Among them:

- **Percent fat free**: A product bearing this claim must be a low-fat or a fat-free product. In addition, the claim must accurately reflect the amount of fat present in 100 g of the food. Thus, if a food contains 2.5 g fat per 50 g, the claim must be "95 percent fat free."

- **Implied**: These types of claims are prohibited when they wrongfully imply that a food contains or does not contain a meaningful level of a nutrient. For example, a product claiming to be made with an ingredient known to be a source of fiber (such as "made with oat bran") is not allowed unless the product contains enough of that ingredient (for example, oat bran) to meet the definition for "good source" of fiber. As another example, a claim that a product contains "no tropical oils" is allowed--but only on foods that are "low" in saturated fat because consumers have come to equate tropical oils with high saturated fat.
- **Meals and main dishes**: Claims that a meal or main dish is "free" of a nutrient, such as sodium or cholesterol, must meet the same requirements as those for individual foods. Other claims can be used under special circumstances. For example, "low-calorie" means the meal or main dish contains 120 calories or less per 100 g. "Low-sodium" means the food has 140 mg or less per 100 g. "Low-cholesterol" means the food contains 20 mg cholesterol or less per 100 g and no more than 2 g saturated fat. "Light" means the meal or main dish is low-fat or low-calorie.
- **Standardized foods**: Any nutrient content claim, such as "reduced fat," "low calorie," and "light," may be used in conjunction with a standardized term if the new product has been specifically formulated to meet FDA's criteria for that claim, if the product is not nutritionally inferior to the traditional standardized food, and the new product complies with certain compositional requirements set by FDA. A new product bearing a claim also must have performance characteristics similar to the referenced traditional standardized food. If the product doesn't, and the differences materially limit the product's use, its label must state the differences (for example, not recommended for baking) to inform consumers.

'Fresh'

Although not mandated by NLEA, FDA has issued a regulation for the term "fresh." The agency took this step because of concern over the term's possible misuse on some food labels.

The regulation defines the term "fresh" when it is used to suggest that a food is raw or unprocessed. In this context, "fresh" can be used only on a food that is raw, has never been frozen or heated, and contains no preservatives. (Irradiation at low levels is allowed.) "Fresh frozen," "frozen fresh," and "freshly frozen" can be used for foods that are quickly frozen while still fresh. Blanching (brief scalding before freezing to prevent nutrient breakdown) is allowed.

Other uses of the term "fresh," such as in "fresh milk" or "freshly baked bread," are not affected.

Baby Foods

FDA is not allowing broad use of nutrient claims on infant and toddler foods. However, the agency may propose claims specifically for these foods at a later date. The terms "unsweetened" and "unsalted" are allowed on these foods, however, because they relate to taste and not nutrient content.

Health Claims

Claims for 10 relationships between a nutrient or a food and the risk of a disease or health-related condition are now allowed. They can be made in several ways: through third-party references (such as the National Cancer Institute), statements, symbols (such as a heart), and vignettes or

descriptions. Whatever the case, the claim must meet the requirements for authorized health claims--for example, they cannot state the degree of risk reduction and can only use "may" or "might" in discussing the nutrient or food-disease relationship. And they must state that other factors play a role in that disease.

The claims also must be phrased so that consumers can understand the relationship between the nutrient and the disease and the nutrient's importance in relationship to a daily diet.

An example of an appropriate claim is: "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."

The allowed nutrient-disease relationship claims and rules for their use are:

- **Calcium and osteoporosis**: To carry this claim, a food must contain 20 percent or more of the Daily Value for calcium (200 mg) per serving, have a calcium content that equals or exceeds the food's content of phosphorus, and contain a form of calcium that can be readily absorbed and used by the body. The claim must name the target group most in need of adequate calcium intakes (that is, teens and young adult white and Asian women) and state the need for exercise and a healthy diet. A product that contains 40 percent or more of the Daily Value for calcium must state on the label that a total dietary intake greater than 200 percent of the Daily Value for calcium (that is, 2,000 mg or more) has no further known benefit.
- **Fat and cancer**: To carry this claim, a food must meet the nutrient content claim requirements for "low-fat" or, if fish and game meats, for "extra lean."
- **Saturated fat and cholesterol and coronary heart disease (CHD)**: This claim may be used if the food meets the definitions for the nutrient content claim "low saturated fat," "low-cholesterol," and "low-fat," or, if fish and game meats, for "extra lean." It may mention the link between reduced risk of CHD and lower saturated fat and cholesterol intakes to lower blood cholesterol levels.
- **Fiber-containing grain products, fruits and vegetables and cancer**: To carry this claim, a food must be or must contain a grain product, fruit or vegetable and meet the nutrient content claim requirements for "low-fat," and, without fortification, be a "good source" of dietary fiber.
- **Fruits, vegetables and grain products that contain fiber and risk of CHD**: To carry this claim, a food must be or must contain fruits, vegetables and grain products. It also must meet the nutrient content claim requirements for "low saturated fat," "low-cholesterol," and "low-fat" and contain, without fortification, at least 0.6 g soluble fiber per serving.
- **Sodium and hypertension (high blood pressure)**: To carry this claim, a food must meet the nutrient content claim requirements for "low-sodium."
- **Fruits and vegetables and cancer**: This claim may be made for fruits and vegetables that meet the nutrient content claim requirements for "low-fat" and that, without fortification, for "good source" of at least one of the following: dietary fiber or vitamins A or C. This claim relates diets low in fat and rich in fruits and vegetables (and thus vitamins A and C and dietary fiber) to reduced cancer risk. FDA authorized this claim in place of an antioxidant vitamin and cancer claim.
- **Folic acid and neural tube defects**: Folic acid and neural tube defects: This claim is allowed on dietary supplements that contain sufficient folate and on conventional foods that are naturally good sources of folate, as long as they do not provide more than 100 percent of the Daily Value for vitamin A as retinol or preformed vitamin A or vitamin D.

A sample claim is "healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect."

- **Dietary sugar alcohols and dental caries (cavities)**: This claim applies to food products, such as candy or gum, containing the sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of any of these. If the food also contains a fermentalbe carbohydrate, such as sugar, the food cannot lower the pH of plaque in the mouth below 5.7. Besides the food ingredient's relationship to dental caries, the claim also must state that frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. A shortened claim is allowed on food packages with less than 15 square inches of labeling surface area.
- **Soluble fiber from certain foods, such as whole oats and psyllium seed husk, and heart disease**: This claim must state that the fiber also needs to be part of a diet low in saturated fat and cholesterol, and the food must provide sufficient soluble fiber. The amount of soluble fiber in a serving of the food must be listed on the Nutrition Facts panel.

Ingredient Labeling

Ingredient declaration is required on all foods that have more than one ingredient.

Because people may be allergic to certain additives and to help them better avoid them, the ingredient list must include, when appropriate:

- FDA-certified color additives, such as FD&C Blue No. 1, by name
- sources of protein hydrolysates, which are used in many foods as flavors and flavor enhancers
- declaration of caseinate as a milk derivative in the ingredient list of foods that claim to be non-dairy, such as coffee whiteners.

As required by NLEA, beverages that claim to contain juice must declare the total percentage of juice on the information panel. In addition, FDA's regulation establishes criteria for naming juice beverages. For example, when the label of a multi-juice beverage states one or more--but not all--of the juices present, and the predominantly named juice is present in minor amounts, the product's name must state that the beverage is flavored with that juice or declare the amount of the juice in a 5 percent range--for example, "raspberry-flavored juice blend" or "juice blend, 2 to 7 percent raspberry juice."

More Information

FDA
General Inquiries: Call toll-free 1-888-INFO-FDA (1-888-463-6332).
Food Safety Hotline: 1-800-332-4010
FDA's food label information on the Web: www.cfsan.fda.gov/label.html.

USDA
Food Safety Education and Communication Office
1400 Independence Ave., S.W., Room 1180
Washington, DC 20250
Meat and Poultry Hotline: 1-800-535-4555.

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U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
A Food Labeling Guide
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A Food Labeling Guide

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Why a Food Labeling Guide?

The Food and Drug Administration (FDA) is responsible for assuring that foods sold in the United States are safe, wholesome and properly labeled. This applies to foods produced domestically, as well as foods from foreign countries. The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act are the Federal laws governing food products under FDA's jurisdiction.

The FDA receives many questions from manufacturers, distributors, and importers about the proper labeling of their food products. This booklet is a summary of the required statements that must appear on food labels under these laws and their regulations. To help minimize legal action and delays, it is recommended that manufacturers and importers become fully informed about the applicable laws and regulations before offering foods for distribution in the United States.

The Nutrition Labeling and Education Act, which amended the FD&C Act requires most foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements. Although final regulations have been established and are reflected in this booklet, regulations are frequently changed. It is the responsibility of the food industry to remain current with the legal requirements for food labeling. All new regulations are published in the Federal Register prior to their effective date and compiled annually in Title 21 of the Code of Federal Regulations. Summaries of new regulations (proposed regulations and final regulations) are posted on the FDA's Internet Website.

In a booklet such as this, it is impractical to attempt to answer every food labeling question that might arise. The most frequently raised questions have been addressed using a "question and answer" format. We believe the vast majority of food labeling questions are answered. They are grouped by the food labeling feature of concern. The Table of Contents will help you locate your food labeling area of interest. The "Key Word Index" will also be helpful in locating specific food labeling concerns.

Under FDA's laws and regulations, label approval is not required to import or distribute a food product. Questions concerning the labeling of food products may be directed to:

Division of Programs and Enforcement Policy (HFS-155)
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204
Telephone (202) 205-5229

The "Food Labeling Questions and Answers", the "Food Labeling Questions and Answers Volume II" and the "Small Business Food Labeling Exemption" are available in the "food" section of FDA's Internet Website. These are invaluable companions to this "Food Labeling Guide" and were developed specifically to address, in detail, the Nutrition Labeling and Education Act requirements.

The regulation numbers referenced for each question in this booklet identify FDA regulations in Title 21, Code of Federal Regulations (21 CFR). Information on ordering FDA's regulations and other food labeling publications appears in Additional FDA Assistance.

September, 1994 (Editorial revisions June, 1999) This document was issued in September 1994 and last revised in June, 1999. For more recent information on Food Labeling. See http://www.cfsan.fda.gov/label.html

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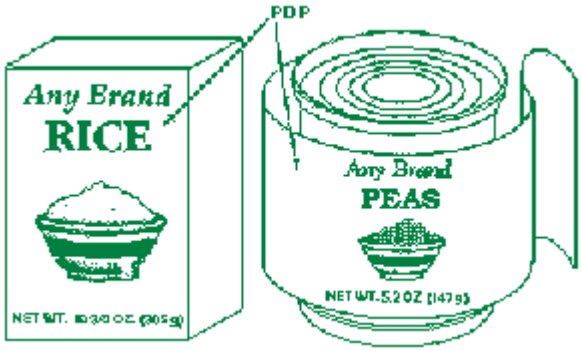
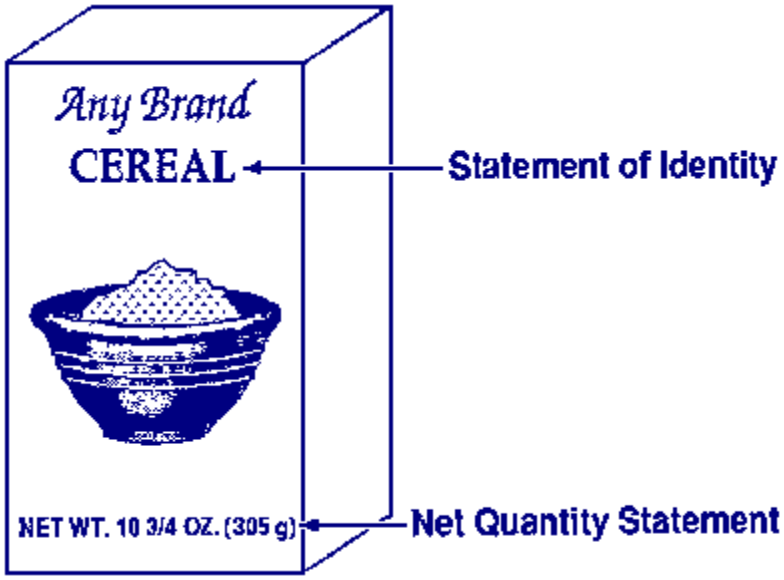
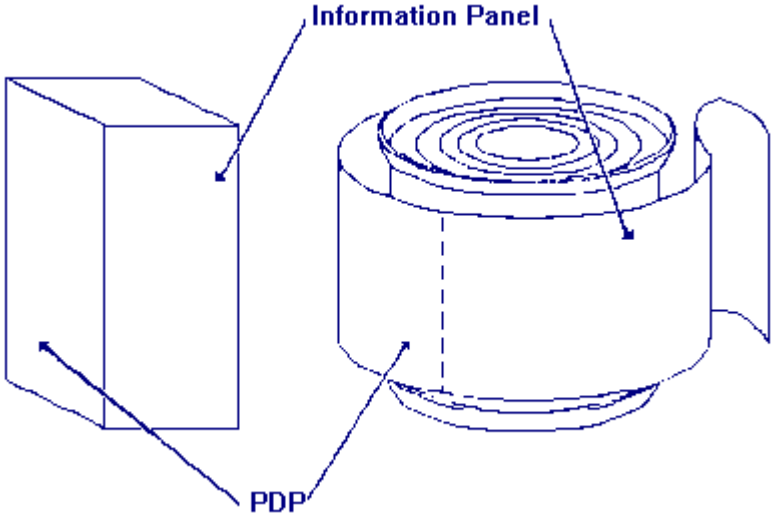
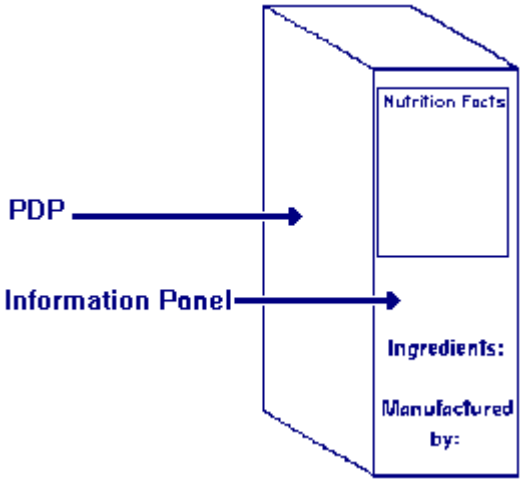
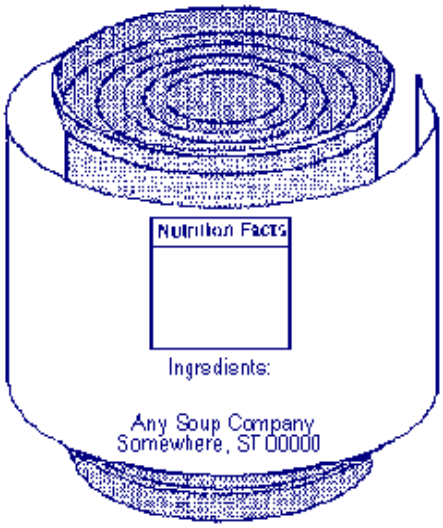
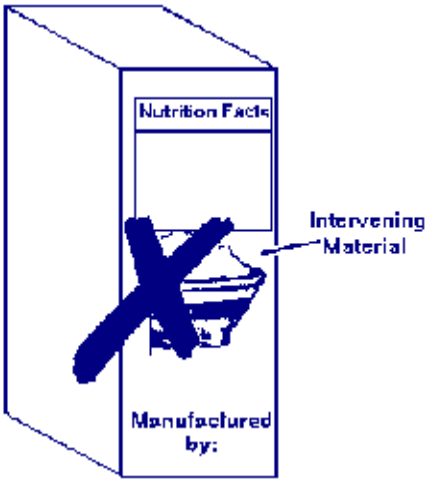
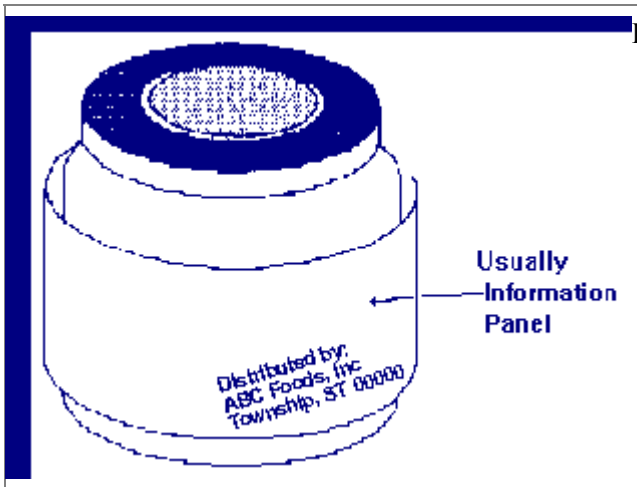
Chapter I--General Food Labeling Requirements

Questions	**Answers**
1. Where should **label statements** be placed on containers and packages?	There are two ways to label packages and containers: a. Place all required label statements on the front label panel (the principal display panel or PDP), or, b. Place certain *specified* label statements on the principal display panel and other labeling on the information panel (the label panel immediately to the right of the principal display panel, as seen by the consumer facing the product).
2. What are the **principal display panel** and the **alternate principal display panel**?	 The principal display panel, or PDP, is that portion of the package label that is most likely to be seen by the consumer at the time of purchase. Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate principal display panels. 21 CFR 101.1

3. What **label statements** must appear on the **principal display panel**?	Place the statement of identity, or name of the food, and the net quantity statement, or amount of product, on the PDP  and on the alternate PDP. The required type size and prominence are discussed in Chapters 2 and 3. 21 CFR 101.3(a) and 101.105(a)
4. Which label panel is the **information panel**?	 The information panel is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (e.g., folded flaps), then the information panel is the next label panel immediately to the right. 21 CFR 101.2(a)

5. What is **information panel labeling**?	 The phrase "information panel labeling" refers to the label statements that are generally required to be placed together, without any intervening material, on the information panel, if such labeling does not appear on the PDP. These label statements include the name and address of the manufacturer, packer or distributor, the ingredient list, and nutrition labeling. 21 CFR 101.2(b) and (d)
6. What **type size, prominence** and **conspicuousness** is required?	For information panel labeling, use a print or type size that is prominent, conspicuous and easy to read. Use letters that are at least one-sixteenth (1/16) inch in height based on the lower case letter "o". The letters must not be more than three times as high as they are wide, and the lettering must contrast sufficiently with the background so as to be easy to read. Do not crowd required labeling with artwork or non-required labeling.  Smaller type sizes may be used for information panel labeling on very small food packages as discussed in 21 CFR 101.2(c). Different type sizes are specified for the nutrition facts label. The type size requirements for the statement of identity and the net quantity statement are discussed in Chapters 2 and 3 of this booklet. 21 CFR 101.2(c) and 101.9(d)(1)(iii)

7. What is the prohibition against **intervening material**?	Nonessential, intervening material is not permitted to be placed between the required labeling on the information panel (e.g., the UPC bar code is not required labeling). 21 CFR 101.2(e) 
8. What **name and address** must be listed on the label?	 Food labels must list: a. Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product, e.g., "manufactured for" or "distributed by." b. Street address if the firm name and address are not listed in a current city directory or telephone book; c. City or town; d. State (or country, if outside the United States); and e. ZIP code (or mailing code used in countries other than the United States). 21 CFR 101.5

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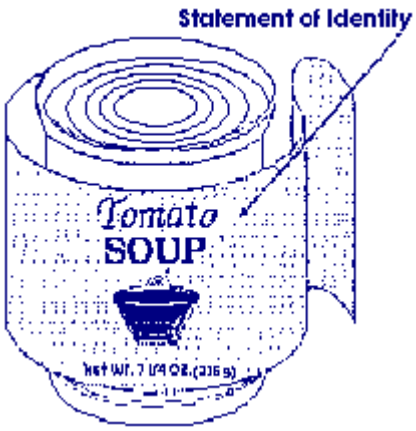
Chapter II--Name of Food

Questions	Answers
1. What is the **name of the food statement** called and where must it be placed?	The statement of identity is the name of the food. It must appear on the front label, or principal display panel as well as any alternate principal display panel. 21 CFR 101.3
2. Should the **statement of identity** stand out?	 Use prominent print or type for the statement of identity. It shall be in bold type. The type size must be reasonably related to the most prominent printed matter on the front panel and should be one of the most important features on the principal display panel. Generally, this is considered to be at least 1/2 the size of the largest print on the label. 21 CFR 101.3(d)
3. What **name** should be used as the **statement of identity**?	The common or usual name of the food, if the food has one, should be used as the statement of identity. If there is none, then an appropriate descriptive name, that is not misleading, should be used. 21 CFR 101.3(b)
4. Where should the **statement of identity** be placed on the label?	Place the statement of identity in lines generally parallel to the base of the package. 21 CFR 101.3(d)

5. When are **fanciful names** permitted as the **statement of identity**?	 When the nature of the food is obvious, a fanciful name commonly used and understood by the public may be used. 21 CFR 101.3(b)(3)
6. Is it necessary to use the **common or usual name** instead of a **new name**?	The common or usual name must be used for a food if it has one. It would be considered misleading to label a food that has an established name with a new name. If the food is subject to a standard of identity it must bear the name specified in the standard. 21 CFR 101.3(b)(2)
7. Should modified **statements of identity** be used for **sliced and unsliced** versions of a food?	 Labels must describe the form of the food in the package if the food is sold in different optional forms such as sliced and unsliced, whole or halves, etc.  21 CFR 101.3(c)
8. What food must be labeled as an **"imitation"**?	 A new food that resembles a traditional food and is a substitute for the traditional food must be labeled as an imitation if the new food contains less protein or a lesser amount of any essential vitamin or mineral.  21 CFR 101.3(e)
9. What **type size** and **degree of prominence**	Use the same type size and prominence for the word "imitation" as is

is required for the word "imitation" in the product name?	used for the name of the product imitated. 21 CFR 101.3(e)
10. What causes a **juice beverage** label to be required to have a **% juice declaration**?	Beverages that purport to contain juice (fruit or vegetable juice) must declare the % of juice. Included are beverages that purport to contain juice by way of label statements, by pictures of fruits or vegetables on the label, or by taste and appearance causing the consumer to expect juice in the beverage. This includes non-carbonated and carbonated beverages, full-strength (100%) juices, concentrated juices, diluted juices, and beverages that purport to contain juice but contain no juice. 21 CFR 101.30(a)
11. **Where** and **how** is **% juice declared**?	The % juice must be on the information panel, near the top. Only the brand name, product name, logo, or universal product code may be placed above it. Use easily legible boldface print or type that distinctly contrasts with the other printed or graphic material. The type size for the % juice declaration must be not less than the largest type on the information panel, except that used for the brand name, product name, logo, universal product code, or the title phrase "Nutrition Facts." The percentage juice declaration may be either "contains ____% juice" or "____% juice." The name of the fruit or vegetable may also be included (e.g., "100% Apple Juice"). 21 CFR 101.30(e)
12. Are there any **exceptions** from the **% juice requirement**?	An exception is that beverages containing minor amounts of juice for flavoring are not required to bear a % juice declaration provided that: (a) The product is described using the term "flavor" or "flavored," (b) The term "juice" is not used other than in the ingredient list, and (c) The beverages do not otherwise give the impression they contain juice. 21 CFR 101.30(c)
13. How is the **% juice calculated**?	Juice expressed directly from fruit or vegetables: Compute on a volume/volume basis. Juice made by adding water to concentrate: Calculate using values from the Brix table in 21 CFR 101.30(h)(1) as

	the basis for 100% juice. 21 CFR 101.30(j), 101.30(h)
14. Should my product be **labeled** as a **"drink"** or a **"beverage"**?	Beverages that are 100% juice may be called "juice." However, beverages that are diluted to less than 100% juice must have the word "juice" qualified with a term such as "beverage," "drink," or "cocktail." Alternatively, the product may be labeled with a name using the form "diluted ____ juice," (e.g. "diluted apple juice"). 21 CFR 102.33(g)
15. Is it necessary to use the term **"concentrate"** on the label?	Juices made from concentrate must be labeled with terms such as "from concentrate," or "reconstituted" as part of the name wherever it appears on the label. An exception is that, in the ingredient statement, the juice is declared as "concentrated ____ juice and water" or "water and concentrated ____ juice," as appropriate. 21 CFR 102.33(g)
16. What **name** is used on a **mixed fruit or vegetable juice beverage**?	When stated, names of juices (except in the ingredient list) must be in descending order of predominance by volume, unless the label indicates that the named juice is used as a flavor. Examples: "Apple, Pear and Raspberry Juice Drink" "Raspberry-Flavored Apple and Pear Juice Drink" If the label represents one or more but not all the juices (except in the ingredient list), then the name must indicate that more juices are present. Examples: "Apple Juice Blend" "Apple Juice in a Blend of Two Other Fruit Juices" When one or more, but not all, juices are named and the named juice is not the predominant juice, the name of the beverage must either state that the beverage is flavored with the named juice or declare the amount of the named juice in a 5% range. Examples: (For a "raspcranberry" beverage that is primarily white grape juice with raspberry and cranberry juices added) "Raspcranberry Raspberry and Cranberry flavored Juice Drink" "Raspcranberry Cranberry and Raspberry Juice Beverage 10-15% Cranberry Juice and 3-8% Raspberry Juice" 21 CFR 102.33(b), 102.33(c), 102.33(d)

17. What **type sizes** must be used for **% juice information**?	<u>Product Name</u> The term "from concentrate" or "reconstituted" must be no smaller than one-half the height of the letters in the name of the juice. The 5% range information generally should be not less than one-half the height of the largest type appearing in the common or usual name (may not be less than 1/16th inch in height on packages with 5 sq. in. or less area on the principal display panel, and not less than 1/8 inch in height on packages with a principal display panel greater than 5 sq. in. <u>Information Panel</u> Use easily legible boldface print or type that distinctly contrasts with the other printed or graphic material on the information panel. The type-size for the %-juice label must be not less than the largest type found on the information panel except that used for the brand name, product name, logo, universal product code, or the title phrase "Nutrition Facts." 21 CFR 101.30(e)(2), 102.5(b)(2), 102.33(d), 102.33(g)

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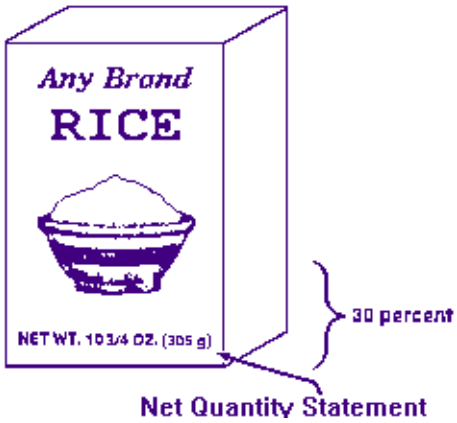
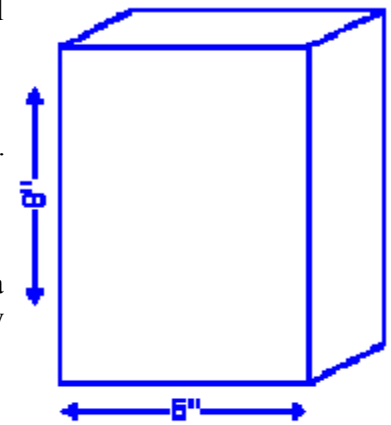
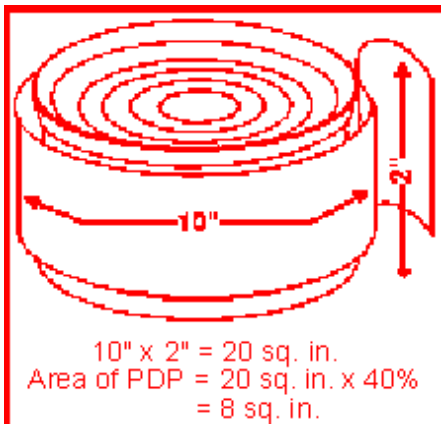
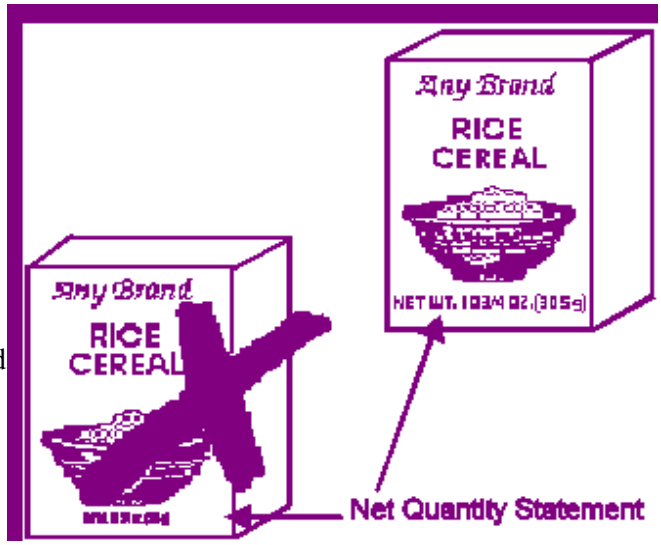
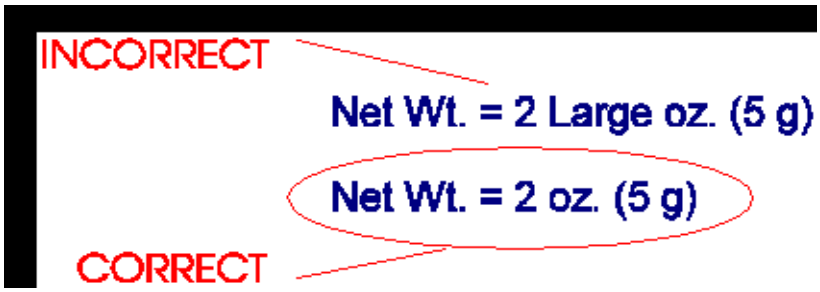
Chapter III--Net Quantity of Contents Statements

Questions	Answers
1. What is the **net quantity of contents**?	The net quantity of contents (net quantity statement) is the statement on the label which provides the amount of food in the container or package. 21 CFR 101.105(a) 
2. Where is the **net quantity of contents statement placed** on the label?	The net quantity statement (net quantity of contents) is placed as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container. 21 CFR 101.105(f)
3. Should the **net quantity of contents** be stated in both **grams** and **ounces**?	Food labels printed must show the net contents in both metric (grams, kilograms, milliliters, liters) and U.S. Customary System (ounces, pounds, fluid ounces) terms. The metric statement may be placed either before or after the U. S. Customary statement, or above or below it. Each of the following examples is correct (additional examples appear in the regulations): • Net wt 1 lb 8 oz (680g) • Net wt 1 lb 8 oz 680 g • 500 ml (1 pt 0.9 fl oz) • Net contents 1 gal

	3.79 L P.L. 102-329, August 3, 1992; 21 CFR 101.105
4. Why is it necessary to calculate the **area** of the **principal display panel**?	The area of the principal display panel (calculated in square inches or square centimeters) determines the minimum type size that is permitted for the net quantity statement (see next question). Calculate the area of the principal display panel as follows. The area of a rectangular or square principal display panel on a carton is the height multiplied by the width (both in inches or both in centimeters).  Area of PDP = 6" x 8" = 48 sq. in.  10" x 2" = 20 sq. in. Area of PDP = 20 sq. in. x 40% = 8 sq. in. To calculate the area of the principal display panel for a cylindrical container, multiply 40% of the height by the circumference.
5. What is the **minimum type size**?	For the net quantity statements, the minimum type size is the smallest type size that is permitted based on the space available for labeling on the principal display panel. Determine the height of the type by measuring the height of the lower case letter "o" or its equivalent when mixed upper and lower case letters are used, or the height of the upper case letters when only upper case letters are used. **Minimum Type Size** — **Area of Principal Display Panel** 1/16 in. (1.6 mm) — 5 sq. in. (32 sq. cm.) or less 1/8 in. (3.2 mm) — More than 5 sq. in. (32 sq. cm.) but not more than 25 sq. in. (161 sq. cm.)

	1/8 in. (3.2 mm) — More than 5 sq. in. (32 sq. cm.) but not more than 25 sq. in. (161 sq. cm.) 3/16 in. (4.8 mm) — More than 25 sq. in. (161 sq. cm.) but not more than 100 sq. in. (645 sq. cm.) 1/4 in. (6.4 mm) — More than 100 sq. in. (645 sq. cm.) but not more than 400 sq. in. (2580 sq. cm.) 1/2 in. (12.7 mm) — Over 400 sq. in. (2580 sq. cm.) 21 CFR 101.105(h) and (i)
6. What are the **conspicuousness** and **prominence** requirements for **net quantity statements**?	Choose a print style that is prominent, conspicuous and easy to read. The letters must not be more than three times as high as they are wide, and lettering must contrast sufficiently with the background to be easy to read. Do not crowd the net quantity statement with artwork or other labeling (minimum separation requirements are specified in the regulation).  21 CFR 101.105 and 101.15
7. What is **included** in the **net quantity of contents statement**?	Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food. **Filled container weighs 18 oz.** **Empty container weighs 2 oz.** **Wrapper weighs 1 oz.** **Net Weight 15 oz. (425 g)** 21 CFR 101.105(g)
8. Is **water** or	The water or other liquid added to food in a container is usually included in

other packing medium included in **determining the net quantity of contents** in a food container?	the net quantity declared on a label. In some cases where the packing medium is normally discarded, the drained weight is given, e.g., olives and mushrooms. **Beans weigh 9 oz.** **Water weighs 4 oz.** **Sugar weighs 1 oz.** **Net Weight 14 oz. (396 g)** 21 CFR 101.105(a)
9. What is the **net quantity** of contents for a **pressurized can**?	The net quantity is the weight or volume of the product that will be delivered from the pressurized container together with the weight or volume of the propellant. **Whipped cream 11.95 oz.** **Propellant .05 oz.** **Net Weight 12 oz. (340 g)** 21 CFR 101.105(g)
10. What is the policy on using **qualifying phrases** in **net quantity statements**?	Do not use qualifying phrases or terms that exaggerate the amount of food.  21 CFR 101.105(o)

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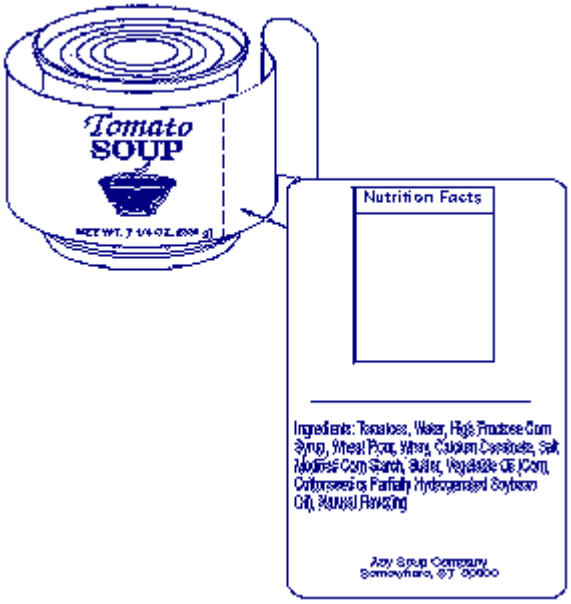
Chapter IV--Ingredient List

Questions	Answers
1. What is the **ingredient list**?	The ingredient list on a food label is the listing of each ingredient in descending order of predominance. **"Ingredients: Pinto Beans, Water, and Salt"** 21 CFR 101.4(a)
2. What is meant by the requirement to list ingredients in **descending order of predominance**?	Descending order of predominance means that the ingredients are listed in order of predominance by weight, that is, the ingredient that weighs the most is listed first, and the ingredient that weighs the least is listed last (see illustration for question #3). 21 CFR 101.4(a)
3.Where is the **ingredient list placed** on the label?	 The ingredient list is placed on the same label panel as the name and address of the manufacturer, packer or distributor. This may be either the information panel or the principal display panel. It may be before or after the nutrition label and the name and address of the manufacturer, packer or distributor. 21 CFR 101.4(a)
4. What **type size** is required for **ingredient lists**?	Use a type size that is at least 1/16 inch in height (lower case "o") and that is prominent, conspicuous, and easy to read. See the type size, prominence, and clarity requirements for information panel labeling

	discussed in the first chapter of this booklet. 21 CFR 101.2(c)
5. Should **water** be listed as an **ingredient**?	Water added in making a food is considered to be an ingredient. The added water must be identified in the list of ingredients and listed in its descending order of predominance by weight. **"INGREDIENTS: Water, Navy Beans, and Salt"** 21 CFR 101.4(a)
6. Should the **common or usual name** always be used for **ingredients**?	Always list the common or usual name for ingredients unless there is a regulation that provides for a different term. For instance, use the term "sugar" instead of the scientific name "sucrose". **"INGREDIENTS: Apples, Sugar, Water, and Spices"** 21 CFR 101.4(a)
7. Is it necessary to declare **trace ingredients**?	It depends on whether the trace ingredient is present in a significant amount and has a function in the finished food. If a substance is an incidental additive and has no function or technical effect in the finished product, then it need not be declared on the label. An incidental additive is usually present because it is an ingredient of another ingredient. Sulfites are considered to be incidental only if present at less than 10 ppm. 21 CFR 101.100(a)(3)
8. What foods may list **alternative fat and oil ingredients**?	Listing alternative fat and oil ingredients ("and/or" labeling) is permitted only in the case of foods that contain relatively small quantities of added fat or oil ingredients (foods in which added fats or oils are not the predominant ingredient) and only if the manufacturer is unable to predict which fat or oil ingredient will be used. **"INGREDIENTS: . . . Vegetable Oil (contains one or more of the following: Corn Oil, Soybean Oil, or Safflower Oil) . . . ."** 21 CFR 101.4(b)(14)
9. What **ingredient listing** is necessary for **chemical preservatives**?	When an approved chemical preservative is added to a food, the ingredient list must include both the common or usual name of the preservative and the function of the preservative by including terms, such as "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor," or "to promote color retention." **"INGREDIENTS: Dried Bananas, Sugar, Salt, and Ascorbic Acid to Promote Color Retention"**

	21 CFR 101.22(j)
10. How are **spices**, **natural flavors** or **artificial flavors** declared **in ingredient lists**?	These may be declared in ingredient lists by using either specific common or usual names or by using the declarations "spices," "flavor" or "natural flavor," or "artificial flavor." **"INGREDIENTS: Apple Slices, Water, Cane Syrup, Corn Syrup, Modified Corn Starch, Spices, Salt, Natural Flavor and Artificial Flavor"** 21 CFR 101.22(h)(1)
11. What **listing** is used for a **spice** that is also a **coloring**?	Spices, such as paprika, turmeric, saffron and others that are also colorings must be declared either by the term "spice and coloring" or by the actual (common or usual) names, such as "paprika." 21 CFR 101.22(a)(2)
12. What **ingredient listing** is used for **vegetable powder**?	Vegetable powders must be declared by common or usual name, such as "celery powder." 21 CFR 101.22(h)(3)
13. What **ingredient listing** is used for **artificial colors**?	It depends on whether the artificial color is a certified color: **<u>Certified colors</u>: List by specific or abbreviated name such as "FD&C Red No. 40" or "Red 40."** **<u>Non-certified colors</u>: List as "artificial color," "artificial coloring," or by their specific common or usual names such as "caramel coloring" and "beet juice."** 21 CFR 101.22(k)(1) and (2), 21 CFR 74.705(d)(2)

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July 9, 2003: For updated examples of nutrition labels
see Examples of Revised Nutrition Facts Panel Listing Trans Fat.

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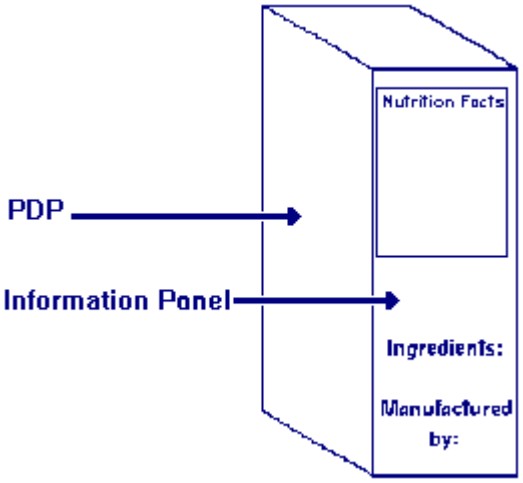
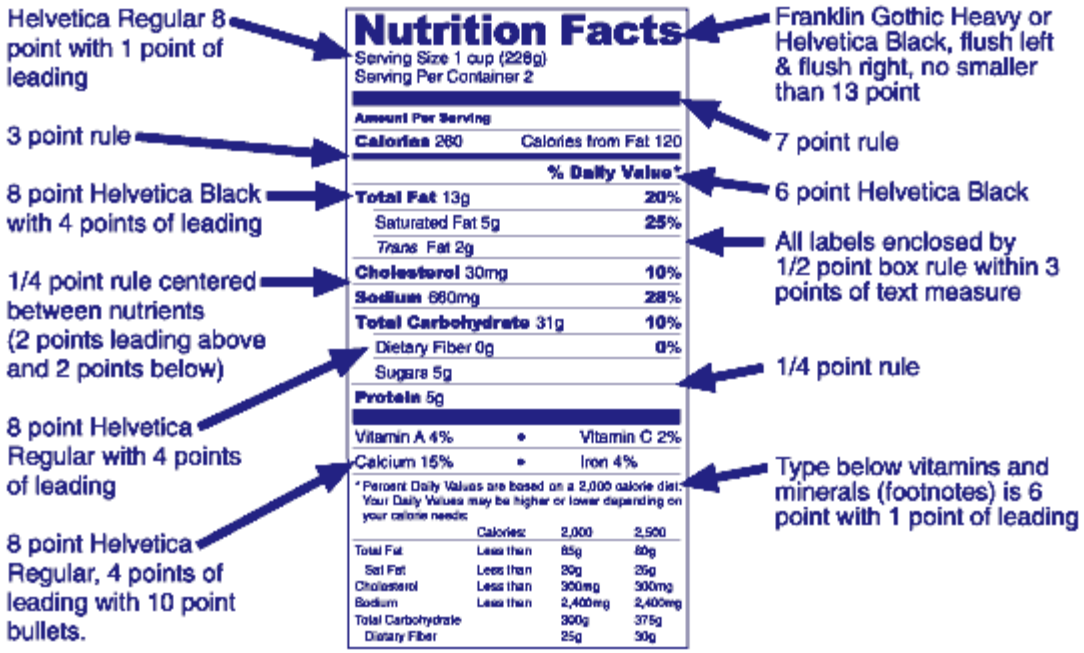
Chapter V--Nutrition Labeling

Questions 1 - 15

Questions	Answers
1. Are **"Nutrition Facts" labels** required on all foods?	The new nutrition label (an example is illustrated in #4 below) is required on most food packages labeled on or after May 8, 1994. The illustration indicates suggested typeface and style to help assure readibility and conspicuousness. Not all of these type specifications are required. The mandatory type specifications are listed in § 101.9(d). Unlike the illustrative examples in this booklet, (1) Any legible type style may be used, not just Helvetica, (2) The heading "Nutrition Facts" must be the largest type size in the nutrition label, i.e., it must be larger than 8-point, but does not need to be 13-point, and (3) There is no specific thickness required for the three bars that separate the central sections of the nutrition label. 21 CFR 101.9(a) and 101.9(a)(1) Below are listed categories providing exemptions or special provisions for nutrition labeling. A food package loses those exemptions, which are asterisked, if a nutrition claim is made or nutrition information is provided: Summary of Exemption — Regulation # *Manufactured by small businesses — 21 CFR 101.9(j)(1) and 101.9(j)(18) *Food served in restaurants, etc. or delivered to homes ready for immediate consumption — 21 CFR 101.9(j)(2)

	*Delicatessen-type food, bakery products and confections that are sold directly to consumers from the location where prepared	21 CFR 101.9(j)(3)
	*Foods that provide no significant nutrition such as instant coffee (plain, unsweetened) and most spices	21 CFR 101.9(j)(4)
	Infant formula, and infant and junior foods to 4 years (modified label provisions for these categories)	21 CFR 101.9(j)(5) and 101.9(j)(7)
	Dietary supplements (must comply with 21 CFR 101.36)	21 CFR 101.9(j)(6)
	Medical foods	21 CFR 101.9(j)(8)
	Bulk foods shipped for further processing or packaging before retail sale	21 CFR 101.9(j)(9)
	*Fresh produce and seafood (a voluntary nutrition labeling program covers these foods through the use of the appropriate means such as shelf labels, signs, and posters)	21 CFR 101.9(j)(10) and 101.45
	Packaged single-ingredient fish or game meat may be labeled on basis of 3-ounce cooked portion (as prepared). Custom-processed fish and game are exempt from nutrition labeling.	21 CFR 101.9(j)(11)
	Certain egg cartons (nutrition information inside lid or on insert in carton)	21 CFR 101.9(j)(14)
	Packages labeled "This unit not labeled for retail sale" within multiunit package, and outer wrapper bears all required label statements	21 CFR 101.9(j)(15)
	Self-service bulk foods--nutrition labeling by placard, or on original container displayed clearly in view	21 CFR 101.9(a)(2) and 101.9(j)(16)
	Donated food that is given free (not sold) to the consumer.	You are not required to put "Nutrition Facts" labels on donated food unless the donated food is later placed on sale (the law applies only to food that is "offered for sale") -- 21 CFR 101.9(a)

	Game meats may provide required nutrition information or labeling in accordance with 21 CFR 101.9(a)(2). 21 CFR 101.9(j)(12)
2. Are **nutrition designations** permitted on **food package labels**?	FDA considers information that is required or permitted in the "Nutrition Facts" panel on the front label or elsewhere on the package to be a nutrient content claim. In such cases, the package label must comply with the regulations for nutrient content claims. 21 CFR 101.13(c)
3. Where should the **"Nutrition Facts" label** be placed on food packages?	 The "Nutrition Facts" label may be placed together with the ingredient list and the name and address (name and address of the manufacturer, packer, or distributor) on the principal display panel (PDP). These three label statements also may be placed on the "information panel" (the label panel adjacent and to the right of the principal display panel, or, if there is insufficient space on the adjacent panel, on the next adjacent panel to the right). On packages with insufficient area on the principal display panel and information panel, the "Nutrition Facts" label may be placed on any alternate panel that can be seen by the consumer. 21 CFR 101.2(b), 101.2(d)(1), and 101.9(j)(17)
4. What are the **minimum type sizes** and other **format requirements** for the "Nutrition Facts" panel? The illustration below (Nutrition Label Format) indicates the suggested typesetting specifications for a "Nutrition Facts" label to be considered conspicuous and adequately formatted. Format requirements are specified in 21 CFR 101.9(d)	



A. Overall

Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral background.

B. Typeface and Size

1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4 (tighter kerning reduces legibility).
2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" is set in Helvetica Regular).
3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.
4. "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.
5. The table labels (for example, "Amount per Serving") are set in 6 point Helvetica Black.
6. Absolute measures of nutrient content (for example, "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.
7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.
8. All type that appears under vitamins and minerals is set in 6 point Helvetica Regular with 1 point of leading.

C. Rules

1. A 7 point rule separates large groupings as shown in the example. A 3 point rule separates calorie information from the nutrient information.
2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example.

Descenders do not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

D. Box

All labels are enclosed by 1/2 point box rule within 3 points of text measure.

5. What can be done if the **regular "Nutrition Facts" label** (i.e., the vertical format) **does not fit** the package?

On packages with more than 40 square inches available to bear labeling, the "side-by-side" format may be used if the regular "Nutrition Facts" label does not fit. In this format, the bottom part of the "Nutrition Facts" label (following the vitamin and mineral information) is placed immediately to the right and separated with a line. If additional vitamins and minerals are listed after iron and the space under iron is inadequate, they may also be listed to the right with a line that sets them apart from the footnotes.

Nutrition Facts
Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving
Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31mg	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Also, if the package has insufficient continuous vertical space (ie., about 3 inches) to accomodate the above format, the nutrition label may be presented in a tabular (i.e., horizontal) display.

Nutrition Facts
Serving Size 2 slices (56g)
Servings per container 10

Calories 140
Calories from Fat 15

Amount/serving	% Daily Value*	Amount/serving	% Daily Value*
Total Fat 1.5g	**2%**	**Total Carbohydrate** 26g	**9%**
Saturated Fat 0.5g	**3%**	Dietary Fiber 2g	**8%**
Trans Fat 0.5g		Sugars 1g	
Cholesterol 0mg	**0%**	**Protein** 4g	
Sodium 280mg	**12%**		

Vitamin A 0% • Vitamin C 0% • Calcium 6% • Iron 6%
Thiamin 15% • Riboflavin 8% • Niacin 10%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

21 CFR 101.9(d)(11)(iii)

6. Is it necessary to include a **calorie conversion footnote** which states that fat, carbohydrate, and protein furnish 9, 4, and 4 calories per gram, respectively?	No, the use of that footnote is optional. 21 CFR 101.9(d)(10)

7. How should **variety packs** (e.g., breakfast cereals) display the nutrition information?

When a package contains two or more packaged foods that are intended to be eaten individually, such as a variety pack of breakfast cereals or when packages may be used interchangably for the same type of food, such as round ice cream containers, the manufacturer may choose to include separate "Nutrition Facts" panels for each food product, or may use an aggregate "Nutrition Facts" panel.

Nutrition Facts	Wheat Squares Sweetened		Corn Flakes Not Sweetened		Mixed Grain Flakes Sweetened	
Serving Size 1 Box	(35g)		(19g)		(27g)	
Servings Per Container	1		1		1	
Amount Per Serving						
Calories	120		70		100	
Calories from Fat	0		0		0	
	% Daily Value*		% Daily Value*		% Daily Value*	
Total Fat	0g	0%	0g	0%	0g	0%
Saturated Fat	0g	0%	0g	0%	0g	0%
Trans Fat	0g		0g		0g	
Cholesterol	0mg	0%	0mg	0%	0mg	0%
Sodium	0mg	0%	200mg	8%	120mg	5%
Potassium	125mg	4%	25mg	1%	30mg	1%
Total Carbohydrate	29g	10%	17g	6%	24g	8%
Dietary Fiber	3g	12%	1g	4%	1g	4%
Sugars	8g		6g		13g	
Protein	4g		1g		1g	
Vitamin A	0%		10%		10%	
Vitamin C	0%		15%		90%	
Calcium	0%		0%		0%	
Iron	10%		6%		20%	
Thiamin	30%		15%		20%	
Riboflavin	30%		15%		20%	
Niacin	30%		15%		20%	
Vitamin B6	30%		15%		20%	

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

21 CFR 101.9(d)(13)(i) & (ii)

8. What are the **special labeling** provisions for **small and intermediate-sized packages**?	Food packages with a surface area of 40 sq. in. or less available for labeling may place the "Nutrition Facts" label on any label panel (not limited to the information panel), may omit the footnotes to the "Nutrition Facts" label if another asterisk is placed at the bottom of the label with the statement "Percent Daily Values are based on a 2,000 calorie diet," and, may also use the tabular display label format.

	Nutrition Facts Serving Size 1/3 cup (56g) Servings about 3 **Calories** 90 Fat Cal. 20 *Percent Daily Values (DV) are based on a 2,000 calorie diet Amount/serving %DV* Amount/serving %DV* **Total Fat** 2g 3% **Total Carb.** 0g 0% Sat. Fat 1g 5% Fiber 0g 0% *Trans* Fat 0.5g Sugars 0g **Cholest.** 10mg 3% **Protein** 17g **Sodium** 200mg 8% Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6% 21 CFR 101.9(j)(13)(ii)(A), (C), and (D)
9. Is there **another exemption** if the tabular display label does not fit on **small and intermediate-sized packages**?	A linear (string) format may be used on food packages with 40 sq. in. or less total surface area available for labeling if the package shape or size cannot accomodate the nutrition information placed in columns on any label panel. **Nutrition Facts** Serv. Size: 1 package, Amount Per Serving: **Calories** 45, Fat Cal. 10, **Total Fat** 1g (2% DV), Sat. Fat 0.5g (3% DV), *Trans* Fat 0.5g, **Cholest.** 0mg (0% DV), **Sodium** 50mg (2% DV), **Total Carb.** 8g (3% DV), Fiber 1g (4% DV), Sugars 4g, **Protein** 1g, Vitamin A (8% DV), Vitamin C (8% DV), Calcium (0% DV), Iron (2% DV). Percent Daily Values (DV) are based on a 2,000 calorie diet. 21 CFR 101.9(j)(13)(ii)(A)
10. Are **abbreviations** permitted on "Nutrition Facts" labels for **small and intermediate-sized packages**?	Food packages with a surface area of 40 sq. in. or less available for labeling may use the following abbreviations in the "Nutrition Facts" label: Label Term — Abbreviation Serving size — Serv size Servings per container — Servings Calories from fat — Fat cal Calories from saturated fat — Sat fat cal Saturated fat — Sat fat Monounsaturated fat — Monounsat fat Polyunsaturated fat — Polyunsat fat Cholesterol — Cholest Total carbohydrate — Total carb Dietary fiber — Fiber Soluble fiber — Sol fiber Insoluble fiber — Insol fiber Sugar alcohol — Sugar alc Other carbohydrates — Other carb 21 CFR 101.9(j)(13)(ii)(B)

11. What is the **"telephone number exemption"** for **small food packages**?	 Small packages (less than 12 sq. in. total surface area available to bear labeling) may be printed with a telephone number or an address to obtain nutrition information. This exemption (using a telephone number or address in place of the "Nutrition Facts" label) is permitted only if there are no nutrient content claims or other nutrition information on the product label. 21 CFR 101.9(j)(13)(i)
12. What is the **minimum type size** for "Nutrition Facts" label on **small packages**?	Small packages (less than 12 sq. in. total surface area available to bear labeling) may use type sizes no smaller than 6 point or all uppercase type of not less than 1/16 inch for all required nutrition information. 21 CFR 101.9(j)(13)(i)(B)
13. What are the **exemptions** for **single-serving containers**?	Single serving containers may omit the "servings per container" declaration. In addition, most single serving containers may omit the metric equivalent portion of the serving size declaration. However, if it is voluntarily included, it must be consistent with the net quantity of contents value. The serving size for single-serving containers must be a description of the container such as: "Serving Size: 1 package" for food in bags, "Serving Size: 1 container" for foods in plastic containers, or "Serving Size: 1 can" as appropriate. Only those few foods that are required to declare drained weights must include the metric equivalent as part of the serving size declaration, e.g., "Serving size: 1 can drained (__g)." 21 CFR 101.9(b)(5)(iv), 101.9(b)(7) & 101.9(d)(3)(ii)

Nutrition Facts
Serving Size 1 can

Amount Per Serving	
Calories 140	
	% Daily Value*
Total Fat 0g	**0%**
Sodium 20mg	**1%**
Total Carbohydrate 36g	**12%**
Sugars 36g	
Protein 0g	

* Percent Daily Values are based on a 2000 calorie diet.

14. If a manufacturer chooses to do so, how may a food be labeled if the labeled food is commonly combined with another food before eating?	The "Nutrition Facts" panel must state the nutrients in the food "as packaged" (i.e., before consumer preparation). However, manufacturers are encouraged to add a second column of nutrition information showing calories, calories from fat and the % Daily Value for the combination of foods eaten. Quantitative amounts (i.e., g/mg) need only be given for the packaged food. However, as shown in this example, a footnote can be added to indicate the amount of nutrients in the added food. Alternatively, the quantitative amounts of the prepared food may be included immediately adjacent to those for the packaged food (e.g., "Sodium 200 mg, 265 mg"). 21 CFR 101.9(e)

Nutrition Facts

Serving Size 1 cup (35g)
Servings Per Container 10

Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	130	170
Calories from Fat	0	0
	% Daily Value**	
Total Fat 0g*	**0%**	**0%**
Saturated Fat 0g	**0%**	**0%**
Cholesterol 0mg	**0%**	**0%**
Sodium 200mg	**8%**	**11%**
Total Carbohydrate 30mg	**10%**	**12%**
Dietary Fiber 4g	**16%**	**16%**
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	0%	15%
Iron	10%	10%

*Amount in Cereal. One half cup skim milk contributes an additional 40 calories, 65 mg sodium, 6g total carbohydrates (6 g sugars), and 4g protein.

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories:	2,000	2,500
Total Fat	Less than		65g	80g
Sat Fat	Less than		20g	25g
Cholesterol	Less than		300mg	300mg
Sodium	Less than		2,400mg	2,400mg
Total Carbohydrate			300g	375g
Dietary Fiber			25g	30g

Calories per gram:
Fat 9 ■ Carbohydrate 4 ■ Protein 4

15. If a manufacturer chooses to do so, what is an example of the **"Nutrition Facts" label** for a food requiring **further preparation by the consumer**?

Nutrition Facts

Serving Size 1/12 package
(44g, about 1/4 cup dry mix)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	140
	% Daily Value**	
Total Fat 5g*	8%	24%
Saturated Fat 2g	10%	13%
Trans Fat 1g		
Cholesterol 0mg	0%	23%
Sodium 300mg	13%	13%
Total Carbohydrate 34g	11%	11%
Dietary Fiber 0g	0%	0%
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

When the nutrient values in the column for the product prepared according to package directions would be identical to the column for the product as packaged (e.g., the only ingredients added during preparation are ingredients such as water), manufacturers may omit the second column and include the amount made as part of the serving size declaration. For example, a dry beverage mix could declare: "Serving Size: 1 tsp dry powder (4 g)(makes 1 cup prepared)."

21 CFR 101.9(b)(7)(v), 101.9(e), 101.9(e)(5)

Chapter V--Nutrition Labeling

Questions 16 - 41

Questions	Answers
16. What are the special aspects of the **"Nutrition Facts" labels** for **products intended for infants and small children**?	"Nutrition Facts" labels for foods specifically for children less than 4 years do not present % Daily Value or footnotes as used on general food supply labels. Also, foods specifically for children less than 2 years of age must not present information on calories from fat and calories from saturated fat and quantitative amounts for saturated fat, polyunsaturated fat, monounsaturated fat and cholesterol. In both cases, % Daily Value is declared only for protein, vitamins, and minerals. Fruit dessert for children less than 2 years old **Nutrition Facts** Serving Size 1 jar (140g) Amount Per Serving **Calories** 110 **Total Fat** 0g **Sodium** 10mg **Total Carbohydrate** 27mg Dietary Fiber 4g Sugars 0g **Protein** 0g % Daily Value Protein 0% • Vitamin A 6% Vitamin C 45% • Calcium 2% Iron 2% 21 CFR 101.9(j)(5)(i) Fruit dessert for children ages 2 years to 4 years **Nutrition Facts** Serving Size 1 jar (140g) Amount Per Serving **Calories** 110 Calories from Fat 0 **Total Fat** 0g Saturated Fat 0g **Cholesterol** 0mg **Sodium** 10mg **Total Carbohydrate** 27mg Dietary Fiber 4g Sugars 0g **Protein** 0g % Daily Value Protein 0% • Vitamin A 6% Vitamin C 45% • Calcium 2% Iron 2% 21 CFR 101.9(j)(5)(ii)
17. Which **nutrients** may be **summarized in a sentence** after the vitamin and mineral listing instead of showing "0 g" on the "Nutrition Facts" label?	The nutrients listed below may be omitted from the list of nutrients and included in a single sentence when present at "zero" levels in a food. This is done by putting the label statement ("not a significant source of _____") immediately below the listing of vitamins A and C, calcium, and iron. Nutrient — Level per serving — Label statement

Calories from fat 21 CFR 101.9(c)(1)(ii)	Less than 0.5 g fat	"Not a significant source of calories from fat"
Saturated fat 21 CFR 101.9(c)(2)(i)	Less than 0.5g of total fat	"Not a significant source of saturated fat"
Cholesterol 21 CFR 101.9(c)(3)	Less than 2 mg	"Not a significant source of cholesterol"
Dietary fiber 21 CFR 101.9(c)(6)(i)	Less than 1g	"Not a significant source of dietary fiber"
Sugars 21 CFR 101.9(c)(6)(ii)	Less than 1g	"Not a significant source of sugars"
Vitamins A and C, calcium, and iron 21 CFR 101.9(c)(8)(iii)	Less than 2% of RDI	"Not a significant source of _____" (listing the vitamins or minerals omitted)

Nutrition Facts

Serving Size 1 cup (245g)
Servings Per Container 2

Amount Per Serving
Calories 60 Calories from Fat 10

% Daily Value*

Total Fat 1g 2%
Sodium 800mg 33%
Total Carbohydrate 10g 3%
Dietary Fiber 0g 4%
Protein 2g

Vitamin A 20% • Vitamin C 4% • Iron 2%

Not a significant source of saturated fat, cholesterol, sugars, or calcium.

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

Calories:	2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

18. Is there a **"Nutrition Facts" format** for a food in which most **nutrients are present in insignificant amounts?**	 **Nutrition Facts** Serving Size 1 can Amount Per Serving **Calories** 140 % Daily Value **Total Fat** 0g 0% **Sodium** 20mg 1% **Total Carbohydrate** 36g 12% Sugars 36g **Protein** 0g *Percent Daily Values are based on a 2,000 calorie diet. A simplified "Nutrition Facts" label may be used if at least seven of the following nutrients are present in insignificant amounts: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron (slightly different rules for labeling foods intended for children less than 2 years). The five core nutrients, shown in bold in the adjoining example, must always appear on all "Nutrition Facts" labels regardless of amounts present in the food. In addition, any of the nutrients required on the full "Nutrition Facts" label that are naturally present or are added to the food must be "declared on the simplified "Nutrition Facts" label. 21 CFR 101.9(f) - List of nutrients, 101.9(f)(1) - "Insignificant" defined, 101.9(c) - "Insignificant" levels listed for nutrients
19. When should a statement be used on **simplified format labels** to list **nutrients present at insignificant amounts**?	A "simplified format label" must include a statement listing "zero" level nutrients when nutrients are added to the food or voluntarily declared on the "Nutrition Facts" label, and when claims are made on the label. In this example, the manufacturer voluntarily lists polyunsaturated and monounsaturated fat, and therefore must add the statement "Not a significant source of _____" with the blank filled in by the names of nutrients present at insignificant levels. 21 CFR 101.9(f)(4)  **Nutrition Facts** Serving Size 1 Tbsp (14g) Servings Per Container 64 Amount Per Serving **Calories** 130 Calories from Fat 130 % Daily Value **Total Fat** 14g 22% Saturated Fat 2g 10% Polyunsaturated Fat 4g Monounsaturated Fat 8g **Sodium** 0mg 0% **Total Carbohydrate** 0g 0% **Protein** 0g Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron. *Percent Daily Values are based on a 2,000 calorie diet.
20. What **other nutrients** can be declared on the "Nutrition Facts" label?	In addition to the nutrients shown on the label in #15 (in chapter V, first part) manufacturers may add calories from saturated fat, or polyunsaturated fat, monounsaturated fat, potassium, soluble and insoluble fiber, sugar alcohol, other carbohydrates, vitamins and minerals for which RDI's have been established, or the percent of vitamin A that is present as beta-carotene. 21 CFR 101.9(c)
21. Is there a **restriction** against **certain nutrients** on the "Nutrition Facts"	Only those nutrients listed in FDA's nutrition regulations, as mandatory or voluntary components of the nutrition label, may be included in the "Nutrition Facts" label.

label?	21 CFR 101.9(c)
22. When must **voluntary nutrients** be listed?	In addition to the nutrients shown on the sample labels in this booklet, other nutrients (listed in FDA's regulations, e.g., thiamin) must be included on a food's "Nutrition Facts" label if the nutrients are added to the food, if the label makes a nutrition claim (such as a nutrient content claim) about them, or if advertising or product literature provides information connecting the nutrients to the food. 21 CFR 101.9(a), 101.9(c), 101.9(c)(8)(ii), & 101.9(c)(8)(ii)(A)-(B)
23. When should the **vitamins and minerals in flour** be listed on the "Nutrition Facts" label?	Generally, FDA only requires that the label declare the vitamins A and C, and the minerals calcium and iron. The other enrichment vitamins and minerals must be declared when they are added directly to the packaged food (e.g., enriched bread), but not when the enriched product is added as an ingredient to another food. NOTE: It is necessary to declare the other vitamins and minerals in the ingredient list. However, if unenriched flour is used, and the enrichment nutrients are added separately, those nutrients (i.e., thiamin, riboflavin, niacin, and folic acid) would have to be declared on the "Nutrition Facts" label. 21 CFR 101.9(c)(8)(ii)(A)-(B), & 101.9(c)(8)(iv)
24. What **terms** must be used **for the serving size**?	The serving size declaration is made up of two parts: a "household measure term" followed by its metric equivalent in grams (g). For beverages, the household measures may be declared as either fluid ounces, cups, or fractions of a cup with the metric equivalent in milliliters (mL). The examples below show permitted declarations. Food — Examples Cookies — "1 cookie (28 g)" or "1 cookie (28 g/1 oz)" Milk, juices, soft drinks — "8 fl oz (240 mL)," or "1 cup (240 mL)" for multiserving containers, or the container (e.g., "1 can") for single serving containers Grated cheese — "1 tablespoon (5 g)" or "1 tablespoon (5 g/0.2 oz) 21 CFR 101.9(b)(2), 101.9(b)(5), 101.9(b)(7), & 101.12(b)
25. Is a **"reference amount"** different from a serving size?	Yes, the reference amount is used to derive a serving size for a particular product. The following example shows how to use the reference amount to determine the serving size for a 16 oz (454g) pizza: ***1st step:*** From the reference amounts table (21 CFR 101.12(b)), you determine that the reference amount for pizza is 140g.

	2nd step: Calculate the fraction of the pizza that is closest to the reference amount of 140g (calculations shown for a pie of net weight 16oz/454g pizza): 1/3 X 454g = 151g 1/4 X 454g = 113g Note that 151g is closer than 113g to the reference amount for pizza (140g) ***3rd step:*** The serving size is the fraction closest to the reference amount together with the actual gram weight for that fraction of the pizza: **Example: "Serving Size 1/3 pie (151g)"** Therefore, the serving size is "1/3 pizza (151g)" for this example, whereas the reference amount is 140g for all pizzas. Note: Sections 101.9(b)(2)(i) (discrete units), 101.9.(b)(2)(ii) (large discrete units), and 101.9(b)(2)(iii) (bulk products) describe how to use the reference amount to derive a serving size. 21 CFR 101.12(b)
26. How is the **serving size calculated** for the "Nutrition Facts" label on a biscuit mix product?	The following example shows how to calculate the serving size for a biscuit mix product and similar products that require further preparation: ***1st step:*** From the reference amounts table (21 CFR 101.12(b)), determine that the reference amount for biscuits is 55g. ***2nd step:*** Determine amount of mix needed to make a 55g biscuit. ***3rd step:*** Determine closest permitted fraction of tablespoon or cup that contains the amount of mix closest to the amount determined in step 2. ***4th step:*** The serving size is the fraction of a tablespoon or cup of biscuit mix determined in step 3 together with the actual gram weight of that measure of biscuit mix as the serving size. Use the form "Serving Size __ cup (__ g)," the blanks filled in with correct values for the product. Reference amounts: 21 CFR 101.12(b)&(c)
27. Is it necessary to	It is not necessary to adjust the size of your cookies to fit the reference amount. For example, if four cookies weigh 28 grams (and five cookies weigh

reformulate the size of a product such as cookies so that the **serving size** weighs exactly the reference amount (i.e., 30g)?	35 grams), declare the number of cookies nearest the reference amount and label with the exact weight of that number of cookies for the serving size: "Serving size 4 cookies (28g)" or "4 cookies (28g/1 oz)." Reference amounts: 21 CFR 101.12(b)
28. What **fractions** must be used to express serving sizes in common household measures?	For cups, these fractions of a cup are allowed household measures: 1/4 cup, 1/3 cup, 1/2 cup, 2/3 cup, 3/4 cup, 1 cup, 1-1/4 cup, etc. If serving sizes are declared in fluid ounces, declare the serving size in whole numbers (such as 4 fl oz, 5 fl oz, 6 fl oz, etc). For tablespoons, the following fractions of a tablespoon are allowed: 1, 1 1/3, 1 1/2, 1 1/4, 1 2/3, 2, and 3 tablespoons. For teaspoons, the fracations of a teaspoon shall be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teaspoons. 21 CFR 101.9(b)(5)(i)
29. For **foods** that are usually **cut into pieces** before serving, what fractions must be used in the serving size declaration?	These fractions must be used in serving sizes for foods such as cakes or pies: "1/2", "1/3", "1/4", "1/5", "1/6", "1/8", "1/9", "1/10", "1/12" and smaller fractions that can be arrived at by further division by 2 or 3. 21 CFR 101.9(b)(2)(ii)
30. For a multi-serving package, what is the **serving size** for a product that is **sliced thinner or thicker** than the reference amount?	The slices are treated as "discrete units." One slice is a single serving if it weighs from 67% to less than 200% of the reference amount. Larger slices (weighing more than 200% of reference amount) may be declared as a serving if the whole slice can reasonably be eaten at a single-eating occasion. For slices weighing between 50%-67% of the reference amount, the serving size may be declared as either one or two slices. For slices weighing less than 50% of the reference amount, the serving size is the number of slices closest to the reference amount. 21 CFR 101.9(b)(2)(i) Reference amounts: 21 CFR 101.12
31. Should a label show **"2-1/2 servings"**?	For packages containing from two to five servings, round the number of servings to the nearest 1/2 serving. *Examples:* "2 servings," "2-1/2 servings," "3 servings," "3-1/2 servings," "4 servings," "4-1/2 servings," and "5 servings." For packages containing five or more servings, round the number of servings to the nearest whole serving. *Examples:* "5 servings," "6 servings," "7 servings." Rounding should be indicated by the term "about" (e.g., "about 6 servings**"). 21 CFR 101.9(b)(8)**

32. Are there **limits** on the size of a package that may be labeled as a **"single serving"**?	Products that are packaged and sold individually are considered to be single servings if they contain less than 200% of the reference amount shown in 21 CFR 101.12. For packages that contain 200% or more of the reference amount, it is the manufacturer's option to label the product as a single serving if the entire contents can reasonably be eaten at one time. 21 CFR 101.9(b)(6)
33. What is the **smallest amount** of food that may be **labeled as two servings**?	The answer depends on the size of the reference amount. For foods with reference amounts less than 100g (solid foods) or 100mL (liquids), packages must contain at least 200% of the reference amount to be labeled as 2 servings. For foods with reference amounts of 100g or 100mL or more, you may choose to label packages containing more than 150% but less than 200% of the reference amount as either one or two servings. 21 CFR 101.9(b)(6). Reference amounts 21 CFR 101.12(b)
34. Should a value of 47 calories be **"rounded up"** to 50 calories or **"rounded down"** to 45 calories?	Calories must be shown as follows: 50 calories or less--Round to nearest 5-calorie increment: **Example: Round 47 calories to "45 calories"** Above 50 calories--Round to nearest 10-calorie increment: **Example: Round 96 calories to "100 calories"** 21 CFR 101.9(c)(1)
35. What is **"total fat"**?	To determine the total fat content of a food, add the weight in grams of all "lipid fatty acids" in the food (e.g., lauric, palmitic, stearic fatty acids) and express as triglycerides. **Total fat = Weight of all individual fatty acids + weight of one unit of glycerol for each three fatty acids** 21 CFR 101.9(c)(2)
36. What **fractions** are used for **"total fat"** on the "Nutrition Facts" label ?	**Below 0.5 grams total fat per serving: Use the declaration "0 g" for total fat.** 0.5 grams to 5 grams total fat: Use 1/2 gram increments rounded to the nearest 1/2 gram. **Examples: 0.5 g, 1 g, 1.5 g, 2 g, 2.5 g, 3 g, 3.5 g, 4 g, 4.5 g, 5 g** Above 5 grams: Use 1 gram increments rounded to the nearest 1 gram (do not use fractions above 5 grams). **Examples: 5 g, 6 g, 7 g, etc.** 21 CFR 101.9(c)(2)
37. How is **"total**	"Total carbohydrate" is calculated by subtracting the weight of crude protein, total fat, moisture, and ash from the total weight ("wet weight") of the sample

carbohydrate" calculated?	of food. 21 CFR 101.9(c)(6)
38. What is meant by **"sugars"** on the "Nutrition Facts" label?	To calculate "sugars" for the nutrition label, determine the weight in grams of all free monosaccharides and disaccharides in the sample of food. The other nutrients declared on the nutrition label are defined in 21 CFR 101.9(c). 21 CFR 101.9(c)(6)(ii)
39. How many **samples** must be **analyzed** to determine the nutrient levels for a product?	The number of samples to analyze for each nutrient is determined by the variability of each nutrient in a food. Fewer analytical samples are generally required for nutrients that are less variable. The variables that affect nutrient levels should be determined, and a sampling plan should be developed to encompass these variables.
40. Is there a problem with **using ingredient composition data bases** to calculate the values for nutrition labeling?	Manufacturers are responsible for nutrition labeling values on their products. If manufacturers choose to use ingredient data bases, they should be assured of the accuracy of the databases and validate the resulting calculations by comparing them with values for the same foods obtained from laboratory analyses. Manufacturers are responsible for the accuracy of the nutrition labeling values on their products. Although FDA specifies the laboratory methods that will be used to evaluate the accuracy of the labeled products, FDA does not specify acceptable sources for the labeled values.
41. What values are used for calculating Daily Values for the nutrition label?	See "Reference Values for Nutritional Labeling".

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
A Food Labeling Guide
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A Food Labeling Guide
Food Labeling CFR References

Chapter VI--Claims

Questions 1 - 25

Questions	Answers
1. What is a **nutrient content claim**?	It is a claim on a food product that directly or by implication characterizes the level of a nutrient in the food (e.g., "low fat" or "high in oat bran"). Nutrient content claims are also known as "descriptors". 21 CFR 101.13(b)
2. What **nutrient levels** must be present in a food **to use nutrient content "descriptors"** on food labels?	The nutrient levels needed to use nutrient content claims are shown in Appendices A and B.
3. If a **nutrient content claim** is **not included** in FDA's regulations, may it be used on a label?	If a claim is provided for an FDA regulation, then it may be used in accordance with that regulation. A firm may also submit a notification for a claim based on an authoritative statement by a U.S. government scientific body under Section 403(r)(2)(G) of the FD&C Act. All other claims are prohibited. 21 CFR 101.13(b)
4. Where are nutrient content claims specifically defined by the agency?	In 21 CFR 101.13, Subpart D of part 101, and parts 105 and 107. 21 CFR 101.13(b)
5. Are there any **requirements** for **nutrient content claims** regarding the **size or style of type**?	Yes. A nutrient content claim may be no more than twice as prominent as the statement of identity (the name of the food). Specifically, the type size of the claim may be no more than two times the type size of the statement of identity. If the style of the type makes the claim unduly prominent compared to the statement of identity, it will be in violation of the regulations (even if the size of the type is appropriate).

	21 CFR 101.13(f)
6. Is there any **additional information** that is required when a **claim is made**?	Yes. A variety of information is required depending on the claim and what information is needed to prevent the claim from being misleading. Nutrition labeling is required for virtually all claims. 21 CFR 101.13(g) & 101.13(n)
7. What is a **disclosure statement**?	It is a statement that calls the consumer's attention to one or more nutrients in the food, that may increase the risk of a disease or health related condition that is diet related. The disclosure statement is required when a nutrient in a food exceeds certain prescribed levels. The disclosure statement identifies that nutrient (e.g. "See nutrition information for sodium content.") 21 CFR 101.13(h)(1)-(3)
8. When is a disclosure statement required?	It is a requirement when a nutrient content claim is made and the food contains one or more of the following nutrients in excess of the levels listed below per reference amount customarily consumed, per labeled serving, or, for foods with small serving sizes, per 50 grams (different levels apply to main dish meal-type products-see question 20): Fat 13.0 grams Saturated Fat 4.0grams Cholesterol 60 milligrams Sodium 480 milligrams CFR 101.13(h)(1)
9. How must the **disclosure statement be presented on the label?**	It must be in legible boldface type, in distinct contrast to other printed or graphic matter and generally in a type size at least as large as the net quantity of contents declaration. It must also be placed immediately adjacent to the claim. 21 CFR 101.13(h)(4)(i)
10. What is meant by **"immediately adjacent to"**?	"Immediately adjacent to" means just that, right next to the claim. There may be no intervening material such as vignettes or other art work or graphics. However, other required information such as the statement of identity (when the claim is part of the statement of identity such as "low fat cheddar cheese"), and special disclosure statements (those required by section 403(r)(2)(A)(iii)-(v)), are permitted between the claim and the disclosure statement. 21 CFR 101.13(h)(4)(ii)
11. Could a statement of identity ever be considered	Yes, if the claim and the statement of identity were separate pieces of information on the label. If the statement of identity and the

"intervening material"?	claim were printed in noticeably different type styles, sizes, colors or locations, for example, if the phrase "low fat" were in a star-burst, the claim and the statement of identity would be considered separate pieces of information. In such cases the referral statement would have to be adjacent to the claim, not separated from it by the statement of identity.
12. How is the **type size** for the **disclosure statement** determined?	The type size for the disclosure statement is the same as that required for the net quantity of contents statement in 21 CFR 101.105(i); for example, for packages with a principal display panel (PDP) of five square inches or less, the disclosure statement must be at least 1/16 inch in height; for packages with a PDP of 5-25 square inches, not less than 1/8 inch; for PDP's 25-100 square inches, not less than 3/16 inch, and for packages with a PDP greater than 100 square inches, not less than 1/4 inch. 21 CFR 101.13(h)(4)(i)
13. Are there any **exceptions** to the **disclosure statement type size** requirements?	Yes. If a claim is less than two times the required size of the net quantity of contents statement, the disclosure statement may be half the size of the claim but not less than 1/16 inch--21 CFR 101.13(h)(4)(i).
14. What are the **disclosure statement type size requirements** for **extremely small packages**?	If a package has less than three square inches of available label space and is an individual serving-size package served with meals in restaurants, the disclosure statement may be 1/32 inch in height. 21 CFR 101.13(h)(4)(i)
15. Are there any situations when a **referral statement** is **not required**?	Yes. If a claim is made on the same panel as that bearing the nutrition information, no disclosure statement is required. 21 CFR 101.13(h)(4)(ii)
16. If **several claims** are made on one panel, is a **disclosure statement required** each time a claim is made?	No. Only one disclosure statement per panel is required if multiple claims are made on a panel and it must be adjacent to the claim printed in the largest type on that panel. 21 CFR 101.13(h)(4)(iii)
17. If **two claims** are made on one panel, both in the same size print, where is the **disclosure statement** placed?	The disclosure statement may be next to either claim.
18. What is a **food** with a **small serving size**?	It is a food with a reference amount of 30 g or less or 2 tablespoons or less. 21 CFR 101.13(h)(1)
19. When are **disclosure**	A meal (see 21 CFR 101.13(l) for definition of a "meal") must be

statements required on **meal-type products**?	labeled with a disclosure statement if it contains (per labeled serving) more than: 26 g of fat, 8 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium 21 CFR 101.13(h)(2) Likewise, a main dish (see 21 CFR 101.13(m) for the definition of a "main dish") must be labeled with a disclosure statement if it contains (per labeled serving) more than: 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium 21 CFR 101.13(h)(3)
20. When may a **"high"** or a **"good source"** claim be made?	A "good source" claim may be made when a food contains at least 10% of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) (both declared on the label as the "Daily Value" (DV)). A "high" claim may be made when a food contains at least 20% of the DV. 21 CFR 101.54(b)(1)
21. May a **"high"** or a **"good source" claim** be made for a nutrient that does not have an established daily value?	No. "High" and "good source" claims are defined as a percentage of the DV. Therefore, nutrients that do not have an established DV are not covered by the definition and may not make "high" or "good source" claims. 21 CFR 101.54(a)
22. Is there any way that a manufacturer can let consumers know that a product contains **nutrients without DV's,** such as omega-3 fatty acids?	A manufacturer may make a statement about a nutrient for which there is no established daily value so long as the claim specifies only the amount of the nutrient per serving and does not imply that there is a lot or a little of that nutrient in the product. Such a claim might be "x grams of omega-3 fatty acids". Such claims must be outside the "Nutrition Facts" box. 21 CFR 101.13(i)(3)
23. May a label make statements using the words **"contains" and "provides"** (e.g., "Contains x grams of omega-3 fatty acids") for **nutrients without DV's**?	To use the words "contains" or "provides" for nutrients without DV's, the specific amount of the nutrient must be stated. The statements "Contains x grams of omega-3 fatty acids per serving" or "Provides x g of omega-3 fatty acids" are permitted. However, "Contains omega-3 fatty acids" or "Provides omega-3

	fatty acids" (without the specific amount statement) would not be permitted. Such claims would be synonyms for a "good source" claim which is not permitted for nutrients that do not have established daily values.
24. Is a statement that describes the percentage of the RDI of a vitamin or mineral in a food outside the nutrition panel a nutrient content claim?	Yes, while these claims are exempt from certain labeling requirements, they are not exempt from bearing a disclosure statement when required. 21 CFR 101.13(b)(1)
25. May a food that is **normally low** in or **free** of a nutrient bear a **"Low" or "Free" claim** if it has an appropriate disclaimer (e.g., fat-free broccoli)?	No. Only foods that have been specially processed, altered, formulated or reformulated so as to lower the amount of nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food may bear such a claim (e.g., "low sodium potato chips")--21 CFR 101.13(e)(1). Other foods may only make a statement that refers to all foods of that type (e.g., "corn oil, a sodium-free food" or "broccoli, a fat-free food") 21 CFR 101.13(e)(2)

Questions	Answers
26. When is a **formulated food** considered to be specially processed and permitted to bear a **"low" or "free" claim**?	If a similar food would normally be expected to contain a nutrient, such as sodium in canned peas, and the labeled food is made in such a manner that it has little or none of the nutrient, then the food is considered specially processed and may bear a "free" or a "low" claim. 21 CFR 101.13(e)(1)
27. If a product is made that does not have a **regular version**, such as a spice mix, and salt is not included in it, may the product be labeled **"sodium free"**?	Yes. FDA would consider that the food was formulated so as not to include the nutrient in the food and therefore it would be eligible to bear a "sodium free" claim if the product otherwise meets the criteria for the term "sodium free".
28. May a **"Fat Free"** claim be made even though the product is essentially 100% fat, for example, a cooking oil spray that has a very small serving size?	Although the food has less than 0.5 grams of fat per reference amount and technically qualifies to make a "fat free" claim, such a claim on a product that is essentially 100% fat would be misleading. Under section 403(a)(1) and 201(n) of the act, the label would have to disclose that the product is 100% fat.

	However, the terms "fat free" and "100% fat" or "all fat" are contradictory and would likely confuse consumers. FDA believes a claim such as "for fat free cooking" is more appropriate, so long as it was not made in a misleading manner and the words "fat free" were not highlighted, printed in a more prominent type, or otherwise set off from the rest of the statement.
29. May a **"Less"** or **"Fewer"** claim be made that compares ready-to-eat cereals to other breakfast options such as sausages or Danish pastries?	The agency would not object to such a claim if it were properly framed in the context of an eating occasion such as "Try a change for breakfast. A serving of this cereal has __% less fat than a serving of Danish pastry". 21 CFR 101.13(j)(1)(i)(A)
30. What is an appropriate **reference food** for a food bearing a **"Light" claim**?	The reference food must be a food or group of foods that are representative of the same type as the food bearing the claim. For example, a chocolate ice cream would use as its reference food other chocolate ice creams 21 CFR 101.13(j)(1)(i)(B). The nutrient value for fat or calories in a reference food that is used as a basis for a "light" claim may be determined in several ways. It may be a value in a representative valid data base, an average value determined from the top three national (or regional) brands of the food, a market basket norm, or where its nutrient value is representative of the food type, an individual food like a market leader 21 CFR 101.13(j)(1)(ii)(A). The nutrient value used as a basis for a 'light' claim should be similar to that calculated by averaging the nutrient values of many of the foods of the type. It should not be the value of a single food or group of foods at the high end of the range of nutrient values for the food. When compared to an appropriate reference food, a "light" food should be a food that the consumer would generally recognize as a food that is improved in its nutrient value compared to other average products of its type 21 CFR 101.13(j)(1)(ii)(A).
31. What is considered to be an **"average nutrient value"**?	It might be a value in a data base that is appropriate for the food, or an average of nutrient levels in several of the leading brands of that type of food. It might also be a market basket norm. In determining an average nutrient value for a particular type of food, a manufacturer should take into account the nutrient variability of the product--21 CFR 101.13(j)(1)(ii)(A). Some types of products are fairly uniform; others, such as chocolate

	chip cookies, are not. Obviously, in products in which there is wide variability among different versions of the same food type, more products should be considered in arriving at an accurate nutrient level.
32. How will anyone know what the **reference food** is and how it was **derived**?	The type of food used as a reference food must be identified on the label as part of the accompanying information. In addition, the regulation requires that manufacturers using calculated nutrient values (averages, norms, etc.) as the basis for a claim be able to provide specific information on how the nutrient values were derived. This information must be available on request to consumers and to appropriate regulatory officials. 21 CFR 101.13(j)(2)(i) & 101.13(j)(1)(ii)(A)
33. How would a label state the **identity** of a **reference food** when the nutrient value used as a reference for the claim was from a data base or was an average of several foods?	The label might state "50 % less fat than regular Italian salad dressing" (on a light Italian dressing) or "half the fat of the average creamy Italian salad dressing" (on a light creamy Italian salad dressing). The label is not required to state that the reference value came from a data base. 21 CFR 101.13(j)(2)(i).
34. What is the appropriate **reference food** for a nutrient content claim on a product that **substitutes** for a food and bears a name that is significantly different from that food?	Examples are vegetable oil spreads that substitute for margarine or butter, and mayonnaise spreads that substitute for mayonnaise. To bear a claim, the labeled food, for example, vegetable oil spread, must be "not nutritionally inferior" to the food that it resembles and for which it substitutes (e.g., margarine). The reference food on which the claim is based should be the food that it resembles and for which it substitutes (e.g., margarine). Definition of "substitute food"-21 CFR 101.13(d), 101.13(j)(1)(i)(A)-(B)
35. Is there any **information** that must be placed on the label when making a **"Light" claim**?	When making "light" claims, as with other relative claims such as "reduced," "less," "fewer," "more," or "added," the label must state each of the following (these are called "accompanying information"): • The percentage or fraction by which the food has been modified, • The reference food, and • The amount of nutrient (that is the subject of the claim) that is in the labeled food and in the reference food. **Example:** **1/3 fewer calories and 50% less fat than our regular cheese cake. Lite cheese cake--200 calories, 4g fat; Regular cheese cake--300 calories, 8g fat per serving**

	21 CFR 101.56(b)(3)(i)-(ii), 101.13(j)(1) & (2)
36. Where must the **accompanying information** be placed?	The percentage or fraction by which the food is modified and the identity of the reference food must be immediately adjacent to the most prominent claim on the label--21 CFR 101.56(b)(3)(i), 101.13(j)(2)(ii). The actual amount of the nutrient in the labeled food and the reference food may be adjacent to the most prominent claim or on the same panel as the nutrition label--21 CFR 101.56(b)(3)(ii), 101.13(j)(2)(iv)(B).
37. What is the most **prominent claim**?	In order, the most prominent claims are: (1) A claim on the principal display panel as a part of or adjacent to the statement of identity; (2) A claim elsewhere on the principal display panel; (3) A claim on the information panel; and, (4) A claim elsewhere on the label or in labeling. 21 CFR 101.13(j)(2)(iii)
38. How large must the accompanying information be?	Generally the type size must be at least 1/16 of an inch in height. However, there are certain exemptions from this type size requirement for packaged foods that meet certain size requirements. Generally, the minimum type size is 1/32 inch for products with a total surface area available to bear labeling of less than 12 square inches. 21 CFR 101.2(c), 101.2(c)(3)(iii)
39. What does **"Fresh"** mean?	When used in a manner which suggests that a food is unprocessed, the term "fresh" means that the food is in a raw state and has not been frozen or subjected to any form of thermal processing or preservation, except: • Waxing raw fruits or vegetables with a wax approved by FDA as a food additive • Use of approved pesticides before or after harvest • Pasteurization of milk • Treatment of raw foods with ionizing radiation in accordance with 21 CFR 179.26 (not exceeding 1 kiloGray when this booklet was prepared) • Treatment with mild chlorine wash or mild acid wash on produce • Refrigeration is also permitted 21 CFR 101.95(c)
40. What do the terms "Fresh	FDA's regulation specifies that "fresh frozen" or "frozen fresh"

Frozen" and "Quickly Frozen" mean?	means the food has been quickly frozen while still fresh (i.e., recently harvested when frozen). Appropriate blanching before freezing is permitted. "Quickly frozen" means freezing using a system such as blast-freezing (i.e., sub-zero Fahrenheit temperature with high-speed forced air directed at the food) for a sufficient length of time to freeze quickly to the center of the food with virtually no deterioration. 21 CFR 101.95(b)
41. What **health claims** are permitted on food labels?	If a claim is provided for in a FDA regulation, then it may be used in accordance with that regulation. A firm may also submit a health claim based on an authoritative statement by a U.S. government scientific body under section 403(r)(3)(c) of the FD&C Act. The qulifications necesary to use health claims provided for by FDA are summarized in Appendix C. 21 CFR 101.9(k)(1), 101.14(c)-(d) & 101.70
42. If **health symbols** (hearts, etc.) are used on food labels, are **special statements** needed?	The requirements are the same for labels with health symbols and for written health claims. For each, the health claim must be permitted under a regulation in 21 CFR Subpart E, and the food must meet the criteria for health claims for total fat, saturated fat, cholesterol, and sodium content. In addition to the symbol, the label must include the same complete health claim information (such as, including the appropriate model claim information next to the health symbol). 21 CFR 101.14(a)(1), 101.14(a)(5) and 101.14(d)(2)(iv)

43. What are the **requirements** to use the word **"Healthy"**?

To be labeled as "Healthy," a food must meet the definition of "low" for fat and saturated fat, and neither cholesterol nor sodium may be present at a level exceeding the disclosure levels in 21 CFR 101.13(h). In addition, the food must comply with definitions and declaration requirements for any specific nutrient content claims.

21 CFR 101.65(d)(2)-(4)

CONDITIONS FOR THE USE OF "HEALTHY"

low fat	**TOTAL FAT** < 5 g fat/RA & 100g	low fat
low sat fat	**SATURATED FAT** < 2 g sat fat/RA & 100g	low sat fat

	SATURATED FAT	
low sat fat	< 2 g sat fat/RA & 100g	low sat fat
	SODIUM Before 1/2003	
≤ 480 mg/RA, /l.s. and /50g if small RA	≤ 480 mg/RA & l.s. and /50 if small RA	≤ 600/l.s.
	SODIUM After 1/2003	
≤ 360 mg/RA, /l.s. and /50g if small RA	≤ 360 mg/RA & l.s. and /50 if small RA	≤ 480/l.s.
	CHOLESTEROL	
≤ disclosure	< 95 mg/RA & 100g	≤ 90 mg/l.s.
	BENEFICIAL NUTRIENTS	
Contains at least 10% of DV/RA for vitamins A, C, calcium, iron, protein, or fiber. Except raw fruits and vegs.; frozen or canned single ingredient fruits and vegs., except that ingredients whose addition does not change the nutrient profile of the fruit or veg. may be added; enriched cereal-grain products that conform to a standard of identity in 21 CFR 136, 137, or 139.		Contains 10% DV/l.s. of 2 nutrients (vit. A, C, calcium, iron, protein, or fiber) for main dish, 3 nutrients for meal
	FORTIFICATION	
Per 21 CFR 104.20	Per 21 CFR 104.20	Per 21 CFR 104.20
	OTHER CLAIMS	
Food complies with established definition and declaration requirements for any specified nutrient content claim.		

NOTE: l.s. = label serving RA = Reference Amount
Small RA = 50 g or less, or 2 tablespoons or less

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A Food Labeling Guide--Appendix A
Food Labeling CFR References

Definitions of Nutrient Content Claims

Nutrient	Free	Low	Reduced/Less	Comments
	Synonyms for "Free": "Zero", "No", "Without", "Trivial Source of", "Negligible Source of", "Dietarily Insignificant Source of" Definitions for "Free" for meals and main dishes are the stated values per labeled serving	Synonyms for "Low": "Little", ("Few" for Calories), "Contains a Small Amount of", "Low Source of"	Synonyms for "Reduced/Less": "Lower" ("Fewer" for Calories) "Modified" may be used in statement of identity Definitions for meals and main dishes are same as for individual foods on a per 100 g basis	For "Free", "Very Low", or "Low", must indicate if food meets a definition without benefit of special processing, alteration, formulation or reformulation; e.g., "broccoli, a fat-free food" or "celery, a low calorie food"

Nutrient	Free	Low	Reduced/Less	Comments
Calories 21 CFR 101.60(b)	Less than 5 cal per reference amount and per labeled serving	40 cal or less per reference amount (and per 50 g if reference amount is small) Meals and main dishes: 120 cal or less	At least 25% fewer calories per reference amount than an appropriate reference food Reference food may not be "Low Calorie" Uses term "Fewer"	"Light" or "Lite": if 50% or more of the calories are from fat, fat must be reduced by at least 50% per reference amount. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per reference amount "Light" or "Lite" meal or main

		per 100 g	rather than "Less"	dish product meets definition for "Low Calorie" or "Low Fat" meal and is labeled to indicate which definition is met For dietary supplements: Calorie claims can only be made when the reference product is greater than 40 calories per serving

Nutrient	Free	Low	Reduced/Less	Comments
Total Fat 21 CFR 101.62(b)	Less than 0.5 g per reference amount and per labeled serving (or for meals and main dishes, less than 0.5 g per labeled serving) Not defined for meals or main dishes	3 g or less per reference amount (and per 50 g if reference amount is small) Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat	At least 25% less fat per reference amount than an appropriate reference food Reference food may not be "Low Fat"	"__% Fat Free": OK if meets the requirements for "Low Fat" 100% Fat Free: food must be "Fat Free" "Light"--see above For dietary supplements: calorie claims cannot be made for products that are 40 calories or less per serving

Nutrient	Free	Low	Reduced/Less	Comments
Saturated Fat 21 CFR 101.62(c)	Less than 0.5 g saturated fat and less than 0.5 g trans fatty acids per reference amount and per labeled serving (or for meals and main dishes, less than 0.5 g saturated fat and less than 0.5 g trans fatty acids per labeled serving) No ingredient that is understood to contain saturated fat	1 g or less per reference amount and 15% or less of calories from saturated fat Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat	At least 25% less saturated fat per reference amount than an appropriate reference food Reference food may not be "Low Saturated Fat"	Next to all saturated fat claims, must declare the amount of cholesterol if 2 mg or more per reference amount; and the amount of total fat if more than 3 g per reference amount (or 0.5 g or more of total fat for "Saturated Fat Free") For dietary supplements: saturated fat claims cannot be made for products that are 40 calories or less per serving

	except as noted below(*)			

Nutrient	Free	Low	Reduced/Less	Comments
Cholesterol 21 CFR 101.62(d)	Less than 2 mg per reference amount and per labeled serving (or for meals and main dishes, less than 2 mg per labeled serving) No ingredient that contains cholesterol except as noted below(*) If less than 2 mg per reference amount by special processing and total fat exceeds 13 g per reference amount and labeled serving, the amount of cholesterol must be "Substantially Less" (25%) than in a reference food with significant market share (5% of market)	20 mg or less per reference amount (and per 50 g of food if reference amount is small) If qualifies by special processing and total fat exceeds 13 g per reference and labeled serving, the amount of cholesterol must be "Substantially Less" (25%) than in a reference food with significant market share (5% of market) Meals and main dishes: 20 mg or less per 100 g	At least 25% less cholesterol per reference amount than an appropriate reference food Reference food may not be "Low Cholesterol"	Cholesterol claims only allowed when food contains 2 g or less saturated fat per reference amount; or for meals and main dish products--per labeled serving size for "Free" claims or per 100 g for "Low" and "Reduced/Less" claims Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per reference amount and labeled serving (or per 50 g of food if reference amount is small), or when the fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products For dietary supplements: cholesterol claims cannot be made for products that are 40 calories or less per serving

Nutrient	Free	Low	Reduced/Less	Comments
Sodium 21 CFR 101.61	Less than 5 mg per reference amount and per labeled serving (or for meals and main dishes, less than 5 mg per labeled serving	140 mg or less per reference amount (and per 50 g if reference amount is small) Meals and	At least 25% less sodium per reference amount than an appropriate reference food Reference food may not be "Low	"Light" (for sodium reduced products): if food is "Low Calorie" and "Low Fat" and sodium is reduced by at least 50% "Light in Sodium": if sodium is reduced by at least 50% per reference

	No ingredient that is sodium chloride or generally understood to contain sodium except as noted below(*)	main dishes: 140 mg or less per 100g	Sodium"	amount. Entire term "Light in Sodium" must be used in same type, size, color & prominence. Light in Sodium for meals = "Low in Sodium" "Very Low Sodium": 35 mg or less per reference amount (and per 50 g if reference amount is small). For meals and main dishes: 35 mg or less per 100 g "Salt Free" must meet criterion for "Sodium Free" "No Salt Added" and "Unsalted" must conditions of use and must declare "This is Not A Sodium Free Food" on information panel if food is not "Sodium Free" "Lightly Salted": 50% less sodium than normally added to reference food and if not "Low Sodium", so labeled on information panel

Nutrient	**Free**	**Low**	**Reduced/Less**	**Comments**
Sugars 21 CFR 101.60(c)	"Sugar Free": Less than 0.5 g sugars per reference amount and per labeled serving (or for meals and main dishes, less than 0.5 g per labeled serving) No	Not Defined. No basis for recommended intake	At least 25% less sugars per reference amount than an appropriate reference food May not use this claim on dietary supplements of vitamins and minerals	"No Added Sugars" and "Without Added Sugars" are allowed if no sugar or sugar containing ingredient is added during processing. State if food is not "Low" or "Reduced Calorie" The terms "Unsweetened" and "No Added Sweeteners" remain as factual statements Claims about reducing dental caries are implied

	ingredient that is a sugar or generally understood to contain sugars except as noted below(*) Disclose calorie profile (e.g., "Low Calorie")			health claims Does not include sugar alcohols

Notes: * Except if the ingredient listed in the ingredient statement has an asterisk that refers to footnote (e.g., "* adds a trivial amount of fat").

- "Reference Amount" = reference amount customarily consumed.
- "Small Reference Amount" = reference amount of 30 g or less or 2 tablespoons or less (for dehydrated foods that are typically consumed when rehydrated with water or a diluent containing an insignificant amount, as defined in 21 CFR 101.9(f)(1), of all nutrients per reference amount, the per 50 g criterion refers to the prepared form of the food).
- When levels exceed: 13 g Fat, 4 g Saturated Fat, 60 mg Cholesterol, and 480 mg Sodium per reference amount, per labeled serving or, for foods with small reference amounts, per 50 g, a disclosure statement is required as part of claim (e.g., "See nutrition information for___content" with the blank filled in with nutrient(s) that exceed the prescribed levels).

A Food Labeling Guide--Appendix B
Food Labeling CFR References

Relative (or Comparative) Claims

Accompanying Information

For all relative claims, percent (or fraction) of change and identity of reference food must be declared in immediate proximity to the most prominent claim. Quantitative comparison of the amount of the nutrient in the product per labeled serving with that in reference food must be declared on information panel.

For "Light" claims: Generally, percentage reduction for both fat and calories must be stated. An exception is that percentage reduction need not be specified for "low-fat" products. Quantitative comparisons must be stated for both fat and calories.

For claims characterizing the level of antioxidant nutrients in a food:

- an RDI must be established for each of the nutrients that are the subject of the claim;
- each nutrient must have existing scientific evidence of antioxidant activity and
- the level of each nutrient must be sufficient to meet the definition for "high," "good source," or "high potency" in 21 CFR 101.54(b),(c), or (e).

Beta-carotene may be the subject of an antioxidant claim when the level of vitamin A present as beta-carotene in the food is sufficient to qualify for the claim.

Reference Food	
"Light" or "Lite"	(1) A food representative of the type of food bearing the claim (e.g., average value of top three brands or representative value from valid data base), (2) Similar food (e.g., potato chips for potato chips), and (3) Not low-calorie and low-fat (except light-sodium foods which must be low-calorie & low-fat).
"Reduced" and "Added"(or Fortified" and "Enriched")	(1) An established regular product or average representative product, and (2) Similar food.
"More" and "Less" (or "Fewer")	(1) An established regular product or average representative product, and (2) A dissimilar food in the same product category which may be generally substituted for the labeled food (e.g., potato chips for pretzels) or a similar food.

Other Nutrient Content Claims

"Lean"	On seafood or game meat that contains less than 10g total fat, 4.5g or less saturated fat, and less than 95mg cholesterol per reference amount and per 100g (for meals & main dishes, meets criteria per 100g and per labeled serving).
"Extra Lean"	On seafood or game meat that contains less than 5g total fat, less than 2g saturated fat and less than 95mg cholesterol per reference amount and per 100g (for meals and main dishes, meets criteria per 100g and per labeled serving).
High Potency	May be used on foods to describe individual vitamins or minerals that are present at 100% or more of the RDI per reference amount or on a multi-ingredient food product that contains 100% or more of the RDI for at least 2/3 of the vitamins and minerals with DV's and that are present in the product at 2% or more of the RDI (e.g., "High potency multivitamin, multimineral dietary supplement tablets")..
"High", "Rich In", or "Excellent Source Of"	Contains 20% or more of the Daily Value (DV) to describe protein, vitamins, minerals, dietary fiber, or potassium per reference amount. May be used on meals or main dishes to indicate that product contains a food that meets definition. May not be used for total carbohydrate.
"Good Source of", "Contains" or "Provides"	10%-19% of the DV per reference amount. These terms may be used on meals or main dishes to indicate that product contains a food that meets definition. May not be used for total carbohydrate.
"More", "Added", "Extra", or "Plus"	10% or more of the DV per reference amount. May only be used for vitamins, minerals, protein, dietary fiber, and potassium.
"Modified"	May be used in statement of identity that bears a relative claim (e.g., "Modified Fat Cheese Cake, contains 35% Less Fat than our Regular Cheese Cake.")
Any Fiber Claim	If food is not low in total fat, must state total fat in conjunction with claim such as "More Fiber".

Implied Claims

- Claims about a food or ingredient that suggests that the nutrient or ingredient are absent or present in a certain amount or claims about a food that suggests a food may be useful in maintaining healthy dietary practices and which are made with an explicit claim (e.g. "healthy, contains 3 grams of fat") are implied claims and are prohibited unless provided for in a regulation by FDA. In addition, the Agency has devised a petition system whereby specific additional claims may be considered.
- Claims that a food contains or is made with an ingredient that is known to contain a particular nutrient may be made if product is "Low" in or a "Good Source" of the nutrient associated with the claim (e.g. "good source of oat bran").

- Equivalence claims: "contains as much [nutrient] as a [food]" may be made if both reference food and labeled food are a "Good Source" of a nutrient on a per serving basis. (e.g. "Contains as much vitamin C as an 8 ounce glass of orange juice").
- The following label statements are generally not considered implied claims unless they are made in a nutrition context: 1) avoidance claims for religious, food intolerance, or other non-nutrition related reasons (e.g. "100% milk free"); 2) statements about non-nutritive substances (e.g. "no artificial colors"); 3) added value statements (e.g. "made with real butter"); 4) statements of identity (e.g. "corn oil" or "corn oil margarine"); and 5) special dietary statements made in compliance with a specific Part 105 provision.

Claims on Foods for Infants and Children Less than 2 Years of Age

Nutrient content claims are not permitted on foods intended specifically for infants and children less than 2 years of age except:

1. Claims describing the percentage of vitamins and minerals in a food in relation to a daily value.
2. Claims on infant formulas provided for in Part 107.
3. The terms "Unsweetened" and "Unsalted" as taste claims.
4. "Sugar Free" and "No Added Sugar" claims on dietary supplements only.

Terms Covered That Are Not Nutrient Content Claims	
"Fresh"	A raw food that has not been frozen, heat processed, or otherwise preserved.
"Fresh Frozen"	Food was quickly frozen while still fresh.

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September 1994 (Editorial revisions June 1999 and November 2000)

A Food Labeling Guide--Appendix C
Food Labeling CFR References
(See updates at end of article)

Health Claims

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Calcium and Osteoporosis--21 CFR 101.72	- High in calcium, - Assimilable (Bioavailable), - Supplements must disintegrate and dissolve, and - Phosphorus content cannot exceed calcium content	Indicates disease depends on many factors by listing risk factors or the disease: Gender--Female. Race--Caucasian and Asian. Age--Growing older. Primary target population: Females, Caucasian and Asian races, and teens and young adults in their bone-forming years. Additional factors necessary to reduce risk: Eating healthful meals, regular exercise. Mechanism relating calcium to osteoporosis: Optimizes peak bone mass. Foods or supplements containing more than 400 mg calcium must state that total intakes of greater than 2,000 mg calcium provide no added benefit to bone health.	Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Sodium and Hypertension-- 21 CFR 101.74	- Low sodium	*Required terms:* - "Sodium", "High blood pressure" Includes physician statement (Individuals with high blood pressure should consult their physicians) if claim defines high or normal blood pressure	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Dietary Fat and Cancer-- 21 CFR 101.73	- Low fat (Fish & game meats: "Extra lean")	*Required terms:* - "Total fat" or "Fat" - "Some types of cancers" or "Some cancers" Does not specify types of fats or fatty acids that may be related to risk of cancer.	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease-- 21 CFR 101.75	- Low saturated fat, - Low cholesterol, and - Low fat (Fish & game meats: "Extra lean")	*Required terms:* - "Saturated fat and cholesterol", - "Coronary heart disease" or "Heart disease" Includes physician statement (individuals with elevated blood total--or LDL--cholesterol should consult their physicians) if claim defines high or normal blood total--and LDL--	While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.

		cholesterol.	

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer-- 21 CFR 101.76	- A grain product, fruit, or vegetable that contains dietary fiber; - Low fat, and - Good source of dietary fiber (without fortification)	*Required terms:* - "Fiber", "Dietary fiber", or "Total dietary fiber" - "Some types of cancer" or "Some cancers" Does not specify types of dietary fiber that may be related to risk of cancer.	Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease- - 21 CFR 101.77	- A fruit, vegetable, or grain product that contains fiber; - Low saturated fat, - Low cholesterol, - Low fat, - At least 0.6 grams of soluble fiber per RA (without fortification), and, - Soluble fiber content provided on label	*Required terms:* - "Fiber", "Dietary fiber", "Some types of dietary fiber", "Some dietary fibers", or "Some fibers" - "Saturated fat" and "Cholesterol" - "Heart disease" or "Coronary heart disease" Includes physician statement ("Individuals with elevated blood total--or LDL--cholesterol should consult their physicians") if claim defines high or normal blood total--and LDL--cholesterol.	Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Fruits and Vegetables and Cancer-- 21 CFR 101.78	- A fruit or vegetable, - Low fat, and - Good source (without fortification) of at least one of the following: • Vitamin A, • Vitamin C, or • Dietary fiber	*Required terms:* - "Fiber", "Dietary fiber", or "Total dietary fiber"; - "Total fat" or "Fat", - "Some types of cancer" or "Some cancers" Characterizes fruits and vegetables as "Foods that are low in fat and may contain Vitamin A, Vitamin C, and dietary fiber." Characterizes specific food as a "Good source" of one or more of the following: Dietary fiber, Vitamin A, or Vitamin C. Does not specify types of fats or fatty acids or types of dietary fiber that may be related to risk of cancer.	Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, Vitamin A, or Vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamin A and C, and it is a good source of ditary fiber.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Folate and Neural Tube Defects-- 21 CFR 101.79	"Good source" of folate (at least 40 mcg folate per serving) - Dietary supplements, or foods in conventional food form that are naturally good sources of folate (i.e., only non-fortified food in conventional food	*Required terms:* - Terms that specify the relationship (e.g., women who are capable of becoming pregnant and who consume adequate amounts of folate) "Folate", "folic acid", "folacin","folate a B vitamin", "folic acid, a B vitamin," "folacin, a	Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.

	form) - The claim shall not be made on products that contain more than 100% of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D - Dietary supplements shall meet USP standards for disintegration and dissolution or otherwise bioavailable -Amount of folate required in N.L.	B vitamin," "neural tube defects", "birth defects, spinal bifida, or anencephaly", "birth defects of the brain or spinal cord -- anencephaly or spinal bifida", "spinal bifida or anencephaly, birth defects of the brain or spinal cord". Must also include information on the multifactorial nature of neural tube defects, and the safe upper limit of daily intake.	
Approved Claims	**Food Requirements**	**Claim Requirements**	**Model Claim, Statements**

Dietary Sugar Alcohol and Dental Caries-- 21 CFR 101.80	-Sugar free -The sugar alcohol must be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination. -When a fermentable carbohydrate is present, the food must not lower plaque pH below 5.7.	*Required terms*: -"does not promote," "may reduce the risk of," "useful [or is useful] in not promoting" or "expressly [or is expressly] for not promoting" dental caries; -"sugar alcohol" or "sugar alcohols" or the name or names of the sugar alcohols, e.g., sorbitol; -"dental caries" or "tooth decay." Includes statement that frequent between meal consumption of foods high in sugars and starches can promote tooth decay. Packages with less than 15 square inches of surface area available for labeling may use a shortened claim.	**Full claim**: Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay. **Shortened claim(on small packages only)**: Does not promote tooth decay.

Approved Claims	**Food Requirements**	**Claim Requirements**	**Model Claim, Statements**
Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease - 21 CFR 101.81	-Low saturated fat -Low cholesterol -Low fat	*Required terms:* - "Heart disease" or "coronary heart disease." - "Soluble fiber"	Soluble fiber from foods such as [*name of soluble fiber source, and, if desired, name of food product*], as part of a diet low in

	-Include either (1) one or more eligible sources of whole oats, containing at least 0.75 g whole oat soluble fiber per RA; or (2) psyllium seed husk containing at least 1.7 g of psyllium husk soluble fiber per RA -Amount of soluble fiber per RA declared in nutrition label. **Eligible Source of Soluble Fiber** (See updated information) Beta (β) glucan soluble fiber from oat bran, rolled oats (or oatmeal), and whole oat flour. Oat bran must provide at least 5.5% β-glucan soluble fiber, rolled oats must provide at least 4% β-glucan soluble fiber, and whole oat flour must provide at least 4% β-glucan soluble fiber or Psyllium husk wih purity of no less than 95%	qualified by either "psyllium seed husk" or the name of the eligible source of whole oat soluble fiber. - "Saturated fat" and "cholesterol." - "Daily dietary intake of the soluble fiber source necessary to reduce the risk of CHD and the contribution one serving of the product makes to this level of intake." **Additional Required Label Statement** Foods bearing a psyllium seed husk health claim must also bear a label statement concerning the need to consume them with adequate amounts of fluids; e.g., "NOTICE: This food should be eaten with at least a full glass of liquid. Eating this product without enough liquid may cause choking. Do not eat this product if your have difficulty in swallowing." (21 CFR 101.17(f))	saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food product*] supplies __ grams of the [necessary daily dietary intake for the benefit] soluble fiber from [*name of soluble fiber source*] necessary per day to have this effect.

Approved Claims	Food Requirements	Claim Requirements	Model Claim, Statements
Soy Protein and Risk of Coronary Heart Disease 21 CFR 101.82	- At least 6.25 g soy protein per RA - Low saturated fat,	*Required terms:* - "Heart disease" or "coronary heart disease" - "Soy protein"	(1) 25 grams of soy protein a day, as part of a diet low in saturated fat and cholesterol, may reduce the risk of

	- Low cholesterol, and - Low fat (except that foods made from whole soybeans that contain no fat in addition to that inherent in the whole soybean are exempt from the "low fat" requirement)	- "Saturated fat" and "cholesterol" Claim specifies daily dietary intake levels of soy protein associated with reduced risk Claim specifies amount of soy protein in a serving of food	heart disease. A serving of [*name of food*] supplies __ grams of soy protein. (2) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [*name of food*] provides __ grams of soy protein.

Approved Claims	**Food Requirements**	**Claim Requirements**	**Model Claim, Statements**
Plant Sterol/stanol esters and Risk of Coronary Heart Disease 21 CFR 101.83	- At least 0.65 g plant sterol esters per RA of spreads and salad dressings, or - At least 1.7 g plant stanol esters per RA of spreads, salad dressings, snack bars, and dietary supplements. - Low saturated fat, - Low cholesterol, and - Spreads and salad dressings that exceed 13 g fat per 50 g must bear the statement "*see nutrition information for fat content*" Salad dressings are exempted from the[minimum 10% DV nutrient requirement (see General Criteria below)	*Required terms:* - " May" or " might" reduce the risk of CHD - " Heart disease" or " coronary heart disease" - " Plant sterol esters" or " plant stanol esters" ; except " vegetable oil" may replace the term " plant" if vegetable oil is the sole source of the sterol/stanol ester Claim specifies plant stero/stanol esters are part of a diet low in saturated fat and cholesterol. Claim does not attribute any degree of CHD risk reduction. Claim specifies the daily dietary intake of plant sterol or stanol esters necessary to	(1) Foods containing at least 0.65 gram per serving of vegetable oil sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 grams, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies __ grams of vegetable oil sterol esters. (2) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 grams of plant stanol esters in two meals may reduce the risk of heart disease. A serving of [*name of food*] supplies __ grams of plant stanol esters.

		reduce CHD risk, and the amount provided per serving. Claim specifies that plant sterol or stanol esters should be consumed with two different meals each a day.	

CLAIMS AUTHORIZED BASED ON AUTHORITATIVE STATEMENTS BY FEDERAL SCIENTIFIC BODIES			
APPROVED CLAIMS	**FOOD REQUIREMENTS**	**CLAIM REQUIREMENTS**	**MODEL CLAIM STATEMENTS**
Whole Grain Foods and Risk of Heart Disease and Certain Cancers Docket No. 99P-2209	- Contains 51 percent or more whole grain ingredients by weight per RA, and - Dietary fiber content at least: • 3.0 g per RA of 55 g • 2.8 g per RA of 50 g • 2.5 g per RA of 45 g • 1.7 g per RA of 35 g - Low fat	*Required wording of the claim:* " Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol may reduce the risk of heart disease and some cancers."	NA
Potassium and the Risk of High Blood Pressure and Stroke Docket No. 00Q-1582	- Good source of potassium - Low sodium - Low total fat - Low saturated fat - Low cholesterol	*Required wording for the claim:* "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."	NA

General Criteria All Claims Must Meet

- All information in one place without intervening material (Reference statement permitted).

- Only information on the value that intake or reduced intake, as part of a total dietary pattern, may have on a disease or health-related condition.
- Enables public to understand information provided and significance of information in the context of a total daily diet.
- Complete, truthful, and not misleading.
- Food Contains, without fortification, 10% or more of the Daily Value for one of six nutrients (dietary supplements excepted):

Vitamin A	500 IU	Calcium	100 mg
Vitamin C	6 mg	Protein	5 g
Iron	1.8 mg	Fiber	2.5 g

- Not represented for infants or toddlers less than 2 years of age.
- Uses "may" or "might" to express relationship between substance and disease.
- Does not quantify any degree of risk reduction.
- Indicates disease depends on many factors.
- Food contains less than the specified levels of four disqualifying nutrients:

Disqualifying Nutrients	Foods	Main Dishes	Meal Products
Fat	13 g	19.5 g	26 g
Saturated Fat	4 g	6 g	8 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

Abbreviations: RA = reference amount, IU = International Units

Chapter VI--Claims

Questions 26 - 45

Questions	Answers
26. When is a **formulated food** considered to be specially processed and permitted to bear a **"low" or "free" claim**?	If a similar food would normally be expected to contain a nutrient, such as sodium in canned peas, and the labeled food is made in such a manner that it has little or none of the nutrient, then the food is considered specially processed and may bear a "free" or a "low" claim. 21 CFR 101.13(e)(1)
27. If a product is made that does not have a **regular version**, such as a spice mix, and salt is not included in it, may the product be labeled **"sodium free"**?	Yes. FDA would consider that the food was formulated so as not to include the nutrient in the food and therefore it would be eligible to bear a "sodium free" claim if the product otherwise meets the criteria for the term "sodium free".
28. May a **"Fat Free"** claim be made even though the product is essentially 100% fat, for example, a cooking oil spray that has a very small serving size?	Although the food has less than 0.5 grams of fat per reference amount and technically qualifies to make a "fat free" claim, such a claim on a product that is essentially 100% fat would be misleading. Under section 403(a)(1) and 201(n) of the act, the label would have to disclose that the product is 100% fat. However, the terms "fat free" and "100% fat" or "all fat" are contradictory and would likely confuse consumers. FDA believes a claim such as "for fat free cooking" is more appropriate, so long as it was not made in a misleading manner and the words "fat free" were not highlighted, printed in a more prominent type, or otherwise set off from the rest of the statement.
29. May a **"Less"** or **"Fewer"** claim be made that compares ready-to-eat cereals to other breakfast options such as sausages or Danish pastries?	The agency would not object to such a claim if it were properly framed in the context of an eating occasion such as "Try a change for breakfast. A serving of this cereal has __% less fat than a serving of Danish pastry". 21 CFR 101.13(j)(1)(i)(A)
30. What is an appropriate **reference food** for a food bearing a **"Light" claim**?	The reference food must be a food or group of foods that are representative of the same type as the food bearing the claim. For example, a chocolate ice cream would use as its reference food other chocolate ice creams

	21 CFR 101.13(j)(1)(i)(B). The nutrient value for fat or calories in a reference food that is used as a basis for a "light" claim may be determined in several ways. It may be a value in a representative valid data base, an average value determined from the top three national (or regional) brands of the food, a market basket norm, or where its nutrient value is representative of the food type, an individual food like a market leader 21 CFR 101.13(j)(1)(ii)(A). The nutrient value used as a basis for a 'light' claim should be similar to that calculated by averaging the nutrient values of many of the foods of the type. It should not be the value of a single food or group of foods at the high end of the range of nutrient values for the food. When compared to an appropriate reference food, a "light" food should be a food that the consumer would generally recognize as a food that is improved in its nutrient value compared to other average products of its type 21 CFR 101.13(j)(1)(ii)(A).
31. What is considered to be an **"average nutrient value"**?	It might be a value in a data base that is appropriate for the food, or an average of nutrient levels in several of the leading brands of that type of food. It might also be a market basket norm. In determining an average nutrient value for a particular type of food, a manufacturer should take into account the nutrient variability of the product--21 CFR 101.13(j)(1)(ii)(A). Some types of products are fairly uniform; others, such as chocolate chip cookies, are not. Obviously, in products in which there is wide variability among different versions of the same food type, more products should be considered in arriving at an accurate nutrient level.
32. How will anyone know what the **reference food** is and how it was **derived**?	The type of food used as a reference food must be identified on the label as part of the accompanying information. In addition, the regulation requires that manufacturers using calculated nutrient values (averages, norms, etc.) as the basis for a claim be able to provide specific information on how the nutrient values were derived. This information must be available on request to consumers and to appropriate regulatory officials. 21 CFR 101.13(j)(2)(i) & 101.13(j)(1)(ii)(A)
33. How would a label state the **identity** of a **reference food** when the nutrient value used as a reference for the	The label might state "50 % less fat than regular Italian salad dressing" (on a light Italian dressing) or "half the fat of the average creamy Italian salad dressing" (on a light creamy Italian salad dressing). The label is not required to state that the

claim was from a data base or was an average of several foods?	reference value came from a data base. 21 CFR 101.13(j)(2)(i).
34. What is the appropriate **reference food** for a nutrient content claim on a product that **substitutes** for a food and bears a name that is significantly different from that food?	Examples are vegetable oil spreads that substitute for margarine or butter, and mayonnaise spreads that substitute for mayonnaise. To bear a claim, the labeled food, for example, vegetable oil spread, must be "not nutritionally inferior" to the food that it resembles and for which it substitutes (e.g., margarine). The reference food on which the claim is based should be the food that it resembles and for which it substitutes (e.g., margarine). Definition of "substitute food"-21 CFR 101.13(d), 101.13(j)(1)(i)(A)-(B)
35. Is there any **information** that must be placed on the label when making a **"Light" claim**?	When making "light" claims, as with other relative claims such as "reduced," "less," "fewer," "more," or "added," the label must state each of the following (these are called "accompanying information"): • The percentage or fraction by which the food has been modified, • The reference food, and • The amount of nutrient (that is the subject of the claim) that is in the labeled food and in the reference food. **Example:** **1/3 fewer calories and 50% less fat than our regular cheese cake. Lite cheese cake--200 calories, 4g fat; Regular cheese cake--300 calories, 8g fat per serving** 21 CFR 101.56(b)(3)(i)-(ii), 101.13(j)(1) & (2)
36. Where must the **accompanying information** be placed?	The percentage or fraction by which the food is modified and the identity of the reference food must be immediately adjacent to the most prominent claim on the label--21 CFR 101.56(b)(3)(i), 101.13(j)(2)(ii). The actual amount of the nutrient in the labeled food and the reference food may be adjacent to the most prominent claim or on the same panel as the nutrition label--21 CFR 101.56(b)(3)(ii), 101.13(j)(2)(iv)(B).
37. What is the most **prominent claim**?	In order, the most prominent claims are: (1) A claim on the principal display panel as a part of or adjacent to the statement of identity;

	(2) A claim elsewhere on the principal display panel; (3) A claim on the information panel; and, (4) A claim elsewhere on the label or in labeling. 21 CFR 101.13(j)(2)(iii)
38. How large must the accompanying information be?	Generally the type size must be at least 1/16 of an inch in height. However, there are certain exemptions from this type size requirement for packaged foods that meet certain size requirements. Generally, the minimum type size is 1/32 inch for products with a total surface area available to bear labeling of less than 12 square inches. 21 CFR 101.2(c), 101.2(c)(3)(iii)
39. What does **"Fresh"** mean?	When used in a manner which suggests that a food is unprocessed, the term "fresh" means that the food is in a raw state and has not been frozen or subjected to any form of thermal processing or preservation, except: • Waxing raw fruits or vegetables with a wax approved by FDA as a food additive • Use of approved pesticides before or after harvest • Pasteurization of milk • Treatment of raw foods with ionizing radiation in accordance with 21 CFR 179.26 (not exceeding 1 kiloGray when this booklet was prepared) • Treatment with mild chlorine wash or mild acid wash on produce • Refrigeration is also permitted 21 CFR 101.95(c)
40. What do the terms "Fresh Frozen" and "Quickly Frozen" mean?	FDA's regulation specifies that "fresh frozen" or "frozen fresh" means the food has been quickly frozen while still fresh (i.e., recently harvested when frozen). Appropriate blanching before freezing is permitted. "Quickly frozen" means freezing using a system such as blast-freezing (i.e., sub-zero Fahrenheit temperature with high-speed forced air directed at the food) for a sufficient length of time to freeze quickly to the center of the food with virtually no deterioration. 21 CFR 101.95(b)
41. What **health claims** are permitted on food labels?	If a claim is provided for in a FDA regulation, then it may be used in accordance with that regulation. A firm may also submit a health claim based on an authoritative statement by a U.S. government scientific body under section 403(r)(3)(c) of the

	FD&C Act. The qulifications necesary to use health claims provided for by FDA are summarized in Appendix C. 21 CFR 101.9(k)(1), 101.14(c)-(d) & 101.70
42. If **health symbols** (hearts, etc.) are used on food labels, are **special statements** needed?	The requirements are the same for labels with health symbols and for written health claims. For each, the health claim must be permitted under a regulation in 21 CFR Subpart E, and the food must meet the criteria for health claims for total fat, saturated fat, cholesterol, and sodium content. In addition to the symbol, the label must include the same complete health claim information (such as, including the appropriate model claim information next to the health symbol). 21 CFR 101.14(a)(1), 101.14(a)(5) and 101.14(d)(2)(iv)

43. What are the **requirements** to use the word **"Healthy"**?

To be labeled as "Healthy," a food must meet the definition of "low" for fat and saturated fat, and neither cholesterol nor sodium may be present at a level exceeding the disclosure levels in 21 CFR 101.13(h). In addition, the food must comply with definitions and declaration requirements for any specific nutrient content claims.

21 CFR 101.65(d)(2)-(4)

CONDITIONS FOR THE USE OF "HEALTHY"

low fat	**TOTAL FAT** < 5 g fat/RA & 100g	low fat
low sat fat	**SATURATED FAT** < 2 g sat fat/RA & 100g	low sat fat
≤ 480 mg/RA, /l.s. and /50g if small RA	**SODIUM**	≤ 600/l.s.
≤ 360 mg/RA, /l.s. and /50g if small RA	**SODIUM**	≤ 480/l.s.
≤ disclosure	**CHOLESTEROL** < 95 mg/RA & 100g	≤ 90 mg/l.s.

CHOLESTEROL		
≤ disclosure	< 95 mg/RA & 100g	≤ 90 mg/l.s.
BENEFICIAL NUTRIENTS		
Contains at least 10% of DV/RA for vitamins A, C, calcium, iron, protein, or fiber. Except raw fruits and vegs.; frozen or canned single ingredient fruits and vegs., except that ingredients whose addition does not change the nutrient profile of the fruit or veg. may be added; enriched cereal-grain products that conform to a standard of identity in 21 CFR 136, 137, or 139.		Contains 10% DV/l.s. of 2 nutrients (vit. A, C, calcium, iron, protein, or fiber) for main dish, 3 nutrients for meal
FORTIFICATION		
Per 21 CFR 104.20	Per 21 CFR 104.20	Per 21 CFR 104.20
OTHER CLAIMS		
Food complies with established definition and declaration requirements for any specified nutrient content claim.		

NOTE: l.s. = label serving RA = Reference Amount
Small RA = 50 g or less, or 2 tablespoons or less

October 2, 2002: Oatrim (amylase-hydrolyzed whole oat flour or oat bran) was added to the eligible sources of oat soluble fiber.

U. S. Department of Health and Human Services
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
A Food Labeling Guide
September, 1994 (Editorial revisions June, 1999)

July 9, 2003: For updated examples of nutrition labels
see Examples of Revised Nutrition Facts Panel Listing Trans Fat.

A Food Labeling Guide
Food Labeling CFR References

Chapter VII--Miscellaneous

Questions	Answers
1. Are **mail order sales** covered by the food labeling laws?	The same labeling laws apply to all categories of retail sale, including mail orders. Foods sold by mail order must be fully labeled.
2. Are **foreign language labels** permitted?	 All required label statements must appear both in English and in the foreign language if any representations appear in a foreign language. 21 CFR 101.15(c)(2)
3. On labels that have two languages, may nutrition information be provided in one "bilingual" "Nutrition Facts" label? When nutrition labeling must be presented in a second language, the nutrition information may be presented in separate nutrition labels for each language **or** in one label with the second language, translating all required information, following that in English. Numeric characters that are identical in both languages need not be repeated.	

Nutrition Facts/Datos De Nutricion

Serving Size/Tamano por Racion 1 cup/1 taza (228g)
Servings Per Container/Raciones por Envase 2

Amount Per Serving/Cantidad por Racion

Calories/Calorias 260 Calories from Fat/Calorias de Grasa 120

	% Daily Value*/% Valor Diaro*
Total Fat/Grasa Total 0g	**20%**
Saturated Fat/Grasa Saturada 5g	**25%**
Cholesterol/Colesterol 30mg	**10%**
Sodium/Sodio 660mg	**28%**
Total Carbohydrate/Carbohidrato Total 31g	**11%**
Dietary Fiber/Fibra Dietetica 0g	**0%**
Sugars/Azucares 5g	
Protein/Proteinas 5g	

Vitamin/ Vitamina A 4% • Vitamin/ Vitamina C 2%

Calcium/ Calcio 15% • Iron/ Hierro 4%

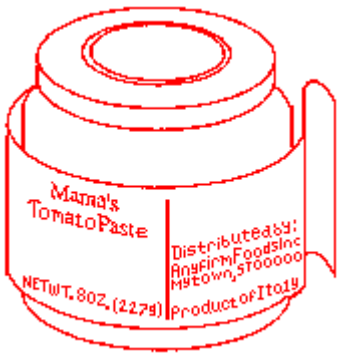
*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

*Los porcentajes de Valores Diaros estan basados en una dieta de 2,000 calorias. Sus valores diarios pueden ser mayores o menores dependiendo de sus necesidades caloricas:

	Calories/Calorias:	2,000	2,500
Total Fat/ Grasa Total	Less than/Menos de	65g	80g
Saturated Fat/ Grasa Saturada	Less than/Menos de	20g	25g
Cholesterol/ Colesterol	Less than/Menos de	300mg	300mg
Sodium/ Sodio	Less than/Menos de	2,400mg	2,400mg
Total Carbohydrate/ Carbohidratos Total		300g	375g
Dietary Fiber/ Fibra Dietetica		25g	30g

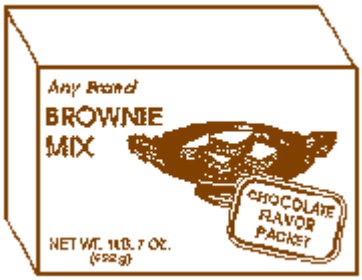
21 CFR 101.9(d)(14)

4. Where should the **country of origin** be declared on an imported food?



The law does not specifically require that the country of origin statement be placed on the principal display panel, but requires that it be conspicuous. If a domestic firm's name and address is declared as the firm responsible for distributing the product, then the country of origin statement must appear in close proximity to the name and address and be at least comparable in size of lettering.

(U.S. Department of Treasury regulation)

5. Which foods require **warning statements**?	 Warnings are required on self-pressurized food containers and on some protein-based weight reduction products and dietary supplements, and on products bearing a health claim regarding the relationship between soluble fiber from psyllium seed husk and reduced risk of coronary heart disease. A warning is also required on products containing saccharin. Place the warning statements on the PDP or on the information panel if there is one. 21 CFR 101.17, Sec. 403(o) of FD&C Act
6. Is it permissible to use **stickers** to make changes in labeling?	Correcting label mistakes in any manner is acceptable if the final label is correct and complies with all regulations at the time of retail sale. The stickers should not cover other mandatory labeling, and should adhere tightly.
7. Are there **restrictions** on **label artwork**?	 Do not use artwork that hides or detracts from the prominence and visibility of required label statements or that misrepresents the food. 21 CFR 1.21(a)(1), 101.3(a), 101.105(h)
8. Does FDA **approve labels** before printing?	No, it is the responsibility of the manufacturer or importer of a food to comply with current food labeling regulations.

Hypertext updated by dms/ear/kwg 2003-JUL-09

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

A Food Labeling Guide
September, 1994 (Editorial revisions June, 1999)

A Food Labeling Guide
Food Labeling CFR References

Reference Values for Nutrition Labeling
(Based on a 2000 Calorie Intake; for Adults and Children 4 or More Years of Age)

NUTRIENT	UNIT OF MEASURE	DAILY VALUES
Total Fat	grams (g)	65
Saturated fatty acids	grams (g)	20
Cholesterol	milligrams (mg)	300
Sodium	milligrams (mg)	2400
Potassium	milligrams (mg)	3500
Total carbohydrate	grams (g)	300
Fiber	grams (g)	25
Protein	grams (g)	50
Vitamin A	International Unit (IU)	5000
Vitamin C	milligrams (mg)	60
Calcium	milligrams (mg)	1000
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)	1000
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)	3400

REV. Jan 30, 1998

Nutrients in this table are listed in the order in which they are required to appear on a label in accordance with 101.9(c)

This list includes only those nutrients for which a Daily Reference Value (DRV) has been established in 101.9(c)(9) or a Reference Daily Intake (RDI) in in 101.9(c)(8)(iv).

A Food Labeling Guide
Food Labeling CFR References

Additional FDA Assistance

Visit FDA's Internet Website - http://www.fda.gov

Publications

The titles that follow are available in FDA's Internet Website

Requirements of the Laws and Regulations Enforced by the Food and Drug Administration

Booklet. Contains basic information on all FDA regulated products. Uses examples examples to explain the more complex laws, regulations and their requirements.

Food Labeling - Questions and Answers Volumes 1 & 2

Vol 1 Question/answer guide for developing or revising food labels.

Vol 2 Question/answer guide to facilitate compliance by restaurants and other retail establishments with regulations issued under NLEA.

FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases

Generic instructions for developing and preparing an acceptable database when valid estimates of nutrient content and variation are not available for the food (single or mixed products) to be labeled.

Small Business Food Labeling Exemption

Sample exemption application form and related information.

The following titles contain more information about Federal food laws and regulations. They can be obtained from the Government Printing Office.

Food and Drug Administration Modernization Act of 1997, Public Law 105-115 GPO (Stock #869-033-00116-9)(Also available from FDA's Internet Website)

Book. Amends the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to Improve the Regulation of Food, Drugs, Devices, and Biological Products.

Compilation of Laws Enforced by the United States Food and Drug Administration and Related Statutes, V. 1 (1996) GPO (Stock #017-012-00378-8)

Printed in 1996, this looseleaf (with binder) is a compilation of the: Federal Food, Drug, and Cosmetic Act; Public Health Service Act; Fair Packaging and Labeling Act; Miscellaneous Provisions Relating to Orphan Drugs; Administrative Procedures Act; Federal Committee Act; and Lead-Based Paint Poisoning Prevention Act.

Title 21, Code of Federal Regulations GPO (order by title and part)

Contains regulations which FDA enforces. Those applicable to the food industry are:

Part 1 to 99 -- General regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act. Color Additives.

Part 100 to 169 -- Food labeling, food standards, good manufacturing practices for foods, low-acid canned foods, and acidified foods.

Part 170 to 199 -- Food additives.

Part 800 to 1299 -- Regulations under Federal Import Milk Act, the Federal Tea Importation Act, the Federal Caustic Poison Act, and regulations for control of communicable diseases and interstate conveyance sanitation.

For price and ordering information

Superintendent of Documents
Government Printing Office
Washington, DC. 20402
Telephone: (202) 512-1800
(Check the telephone book for GPO branches in your city)

FDA District Offices

Hypertext updated by dms/ear 2000-AUG-31

CFSAN/Office of Nutritional Products, Labeling, and Dietary Supplements
September 2003

Claims That Can Be Made for Conventional Foods and Dietary Supplements

Claims that can be used on food and dietary supplement labels fall into three categories: health claims, nutrient content claims, and structure/function claims. The responsibility for ensuring the validity of these claims rests with the manufacturer, FDA, or, in the case of advertising, with the Federal Trade Commission.

I. Health Claims

Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. There are three ways by which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food or dietary supplement: 1) the 1990 Nutrition Labeling and Education Act (NLEA) provides for FDA to issue regulations authorizing health claims for foods and dietary supplements after FDA's careful review of the scientific evidence submitted in health claim petitions; 2) the 1997 Food and Drug Administration Modernization Act (FDAMA) provides for health claims based on an authoritative statement of a scientific body of the U.S. government or the National Academy of Sciences; such claims may be used after submission of a health claim notification to FDA; and 3) the 2003 FDA *Consumer Health Information for Better Nutrition Initiative* provides for qualified health claims where the quality and strength of the scientific evidence falls below that required for FDA to issue an authorizing regulation. Such health claims must be qualified to assure accuracy and non-misleading presentation to consumers. The differences between these three methods of oversight for health claims are summarized below. Appendix C of *The Food Labeling Guide* contains a summary of those health claims that have been approved for use on food and dietary supplement labels: http://www.cfsan.fda.gov/~dms/flg-6c.html.

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 considered to be dietary guidance rather than health claims, provided that the context of the statement does not suggest that a specific substance is the subject. Dietary guidance statements used on food labels must be truthful and non-misleading. Statements that address a role of a specific substance in maintaining normal healthy structures or functions of the body are considered to be structure/function claims. Structure/function claims may not explicitly or implicitly link the relationship to a disease or health related condition. Unlike health claims, dietary guidance statements and structure/function claims are not subject to FDA review and authorization. There are some regulatory requirements associated with the use of structure/function claims; see http://www.cfsan.fda.gov/~dms/labstruc.html.

NLEA Authorized Health Claims. The Nutrition Labeling and Education Act (NLEA) of 1990, the Dietary Supplement Act of 1992, and the Dietary Supplement Health and Education Act of 1994 (DSHEA), provide for health claims used on labels that characterize a relationship between a food, a food component, dietary ingredient, or dietary supplement and risk of a disease (for example, "diets high in calcium may reduce the risk of osteoporosis"), provided the claims meet certain criteria and are authorized by an FDA regulation. FDA authorizes these types of health claims based on an extensive review of the scientific literature, generally as a result of the submission of a health claim petition, using the significant scientific agreement standard to determine that the nutrient/disease relationship is well established. For an explanation of the significant scientific agreement standard, see: http://www.cfsan.fda.gov/~dms/ssaguide.html.

Health Claims Based on Authoritative Statements. The Food and Drug Administration Modernization Act of 1997 (FDAMA) provides a second way for the use of a health claim on foods to be authorized. FDAMA allows certain health claims to be made as a result of a successful notification to FDA of a health claim based on an "authoritative statement" from a scientific body of the U.S. Government or the National Academy of Sciences. FDA has prepared a guide on how a firm can make use of authoritative statement-based health claims. This guide can be found at: http://www.cfsan.fda.gov/~dms/hclmguid.html. FDAMA does not include dietary supplements in the provisions for health claims based on authoritative statements. Consequently, this method of oversight for health claims cannot be used for dietary supplements at this time. Examples of health claims based on authoritative statements may also be found at: http://www.cfsan.fda.gov/~dms/flg-6c.html.

Qualified Health Claims. FDA's 2003 *Consumer Health Information for Better Nutrition Initiative* 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 this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Qualifying language is included as part of the claim to indicate that the evidence supporting the claim is limited. Both conventional foods and dietary supplements may use qualified health claims. 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 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. 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.cfsan.fda.gov/~dms/hclmgui3.html. Qualified health claim petitions that are submitted to FDA will be available for public review and comment. A listing of petitions open for public comment is at the FDA Dockets Management website. A summary of the qualified health claims authorized by FDA may be found at: http://www.cfsan.fda.gov/~dms/qhc-sum.html. For more information on Qualified Health Claims, see http://www.cfsan.fda.gov/~dms/lab-qhc.html.

II. Nutrient Content Claims

The Nutrition Labeling and Education Act of 1990 (NLEA) permits the use of label claims that characterize the level of a nutrient in a food (i.e., nutrient content claims) made in accordance with FDA's authorizing regulations. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as *free*, *high*, and *low*, or they compare the level of a nutrient in a food to that of another food, using terms such as *more*, *reduced*, and *lite*. An accurate quantitative statement (e.g., 200 mg of sodium) that does not "characterize" the nutrient level may be used to describe any amount of a nutrient present. However, a statement such as "only 200 mg of sodium" characterizes the level of sodium as being low and would therefore need to conform to the criteria of an appropriate nutrient content claim or carry a disclosure statement that it does not comply with the claim. Most nutrient content claim regulations apply only to those nutrients or dietary substances that have an established daily value: http://www.cfsan.fda.gov/~dms/flg-7a.html. The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as *high* or *low*, are used consistently for all types of food products and are thus meaningful to consumers. *Healthy* has been defined by a regulation as an implied nutrient content claim that characterizes a food that has "healthy" levels of total fat, saturated fat, cholesterol and sodium. Percentage claims for dietary supplements are another category of nutrient content claims. These claims are used to describe a percentage level of a dietary ingredient for which there is no established Daily Value. Examples include simple percentage statements such as "40% omega-3 fatty acids, 10 mg per capsule," and comparative percentage claims, e.g., "twice the omega-3 fatty acids per capsule (80 mg) as in 100 mg of menhaden oil (40 mg)." (See 21 CFR 101.13(q)(3)(ii): http://www.cfsan.fda.gov/~lrd/cf101-13.html.) A summary of the rules for use of nutrient content claims can be found in Chapter VI of The Food Labeling Guide: http://www.cfsan.fda.gov/~dms/flg-toc.html. Examples of nutrient content claims can be found in Appendices A and B of The Food Labeling Guide: http://www.cfsan.fda.gov/~dms/flg-6a.html and http://www.cfsan.fda.gov/~dms/flg-6b.html.

III. Structure/Function Claims

Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. However, the Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory procedures for such claims for dietary supplement labels. Structure/function claims describe the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient. Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States. The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-approved by FDA but must be truthful and not misleading. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. Further information regarding structure/function claims can be found in FDA's January 9, 2002 Structure/Function Claims Small Entity Compliance Guide: http://www.cfsan.fda.gov/~dms/sclmguid.html. Manufacturers of dietary supplements that make structure/function claims on labels or in labeling must submit a notification to FDA no later than 30 days after marketing the dietary supplement that includes the text of the structure/function claim.

European Union Labeling Regulations

Community legislation on the labeling of foodstuffs includes general provisions on the labeling of foodstuffs to be delivered to the consumer, as laid out in European Parliament and Council Directive 2000/13/EC of 20 March 2000, and labeling provisions contained in legislations which apply to specific products, such as beef or chocolate Directive N° 2000/13/EC has been amended by Commission Directive 2001/101/EC of 26 November 2001 regulating the definition of meat for labeling purpose, where meat is used as an ingredient in foodstuffs, and by Directive 2003/89/EC of 10 November 2003, as regard indication of the ingredients present in foodstuffs.
This last amendment makes obligatory for all ingredients to be indicated on the label.

The new labeling rules in particular aim to ensure that consumers suffering from food allergies or who wish to avoid eating certain ingredients for any other reason are informed. They foresee that all ingredients in foodstuffs will have to be included on the label and abolish the "25% rule" which up to now meant that it is was not obligatory to label the components of compound ingredients that make up less than 25% of the final food product. The new Directive also establishes a list of ingredients liable to cause allergies or intolerances; alcoholic beverages will also have the obligation to mention allergens on their labels. However, since it is possible that some ingredients or substances, derived from allergens, are not likely to be a risk for allergic peoples, the Directive establishes, during a transitional period, a procedure which allows the industry to provide scientific justification for that, and to obtain a provisional labeling exemption for these ingredients or substances. Guidelines have been adopted by the Commission' services for the implementation of this procedure.

Council Directive N° 2000/13/EC on labeling, presentation and advertising of foodstuffs to the final consumer is the main piece of EU legislation regarding the labeling of foodstuffs. This Directive is based upon the principle of functional labeling. Its aim is to ensure that the consumer gets all the essential information as regards the composition of the product, the manufacturer, methods of storage and preparation, etc. Producers and manufacturers are free to provide whatever additional information they wish, provided that it is accurate and does not mislead the consumer. Furthermore, this Directive prohibits the attribution to any foodstuff of the property of preventing, treating or curing a human disease, or reference to such properties Corrigendum to Directive N° 2000/13/EC.

Finally, because labeling, tends to be complex and unclear, which goes against the sought objective and involves additional difficulties in application and control of the applicable provisions, the Commission has also taken steps, in close co-operation with the representatives of the Member States, of consumers, of industry and of trade, to engage in making an evaluation of legislation on labeling, from a modernisation and simplification point of view. Indeed, consumers today express a particularly strong expectation for complete and precise information on foodstuffs. The conclusions of this study have been recently finalized. They identify the key points on which the Commission will now have to focus for drawing-up a future proposal with a view to modernising the Community legislation on labeling. It is expected that such a proposal could be put forward in 2005, following a consultation process with all interested parties.

The History of Bar Codes

Although we don't give them much special attention now, the bar codes that we see around us all the time today did not even exist a few decades ago. We will explore some the history of bar coding and how it came to the stage it is at today.

Early History

It was retail applications which drove the early technological developments of bar coding, but industrial applications soon followed. Wallace Flint was the first person to suggest an automated checkout system in 1932, and although Flint's system was economically unfeasible, it was an important step toward the bar codes we have today. 40 years later, Flint, as vice-president of the National Association of Food Chains, supported the efforts which led to the Uniform Product Code (UPC). Several code formats were developed in the 1940s, 1950s, and 1960s, including a bull's-eye code, numeral codes, and various formats of bar codes.

Initial Uses of Bar Codes

Serious efforts toward automating supermarket point-of-sale started in the late 1960s, and beginning in 1972 a Kroger store in Cincinnati operated using a bull's-eye code. Meanwhile, a committee was formed within the grocery industry to select a standard code to be used in the industry. Proposals were solicited from various interested parties, and on April 3, 1973, the committee selected the UPC symbol (based on the proposal from IBM) as the industry standard. The success of the system since then has spurred on the development of other coding systems.

Computers and Bar Codes

As computer systems have become more advanced, bar codes have become even more prevalent in our society. Now many retail stores, from supermarkets to hardware stores, use bar codes, and they are used in many industrial and military applications as well. With ever-increasing use, many companies have developed software to generate and manipulate bar codes. A few of these companies include: TAL Technologies, RiversEdge, and Bar Code Pro. As newer technologies are developed, we may eventually see a disappearance of bar codes as we know them today, but for the present time bar codes are alive and well.

This page provides basic information about the Universal Product Code (UPC). There are sections on the symbol, the bars themselves, the check digit, and scanning.

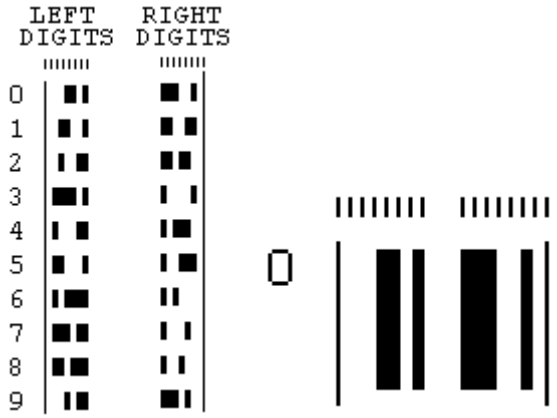
The UPC Symbol

Glancing at the UPC symbol above, you can easily see that it is divided in half. In fact, a UPC symbol can be divided into seven parts. We will consider these parts one at a time, starting from the left:

1. The first part of a UPC symbol is the left guard pattern. This consists of two thin vertical lines a bit taller than the other bars. The guard pattern doesn't contribute to the actual code, but is simply an indicator to identify the start of a UPC symbol.
2. The second part of a UPC symbol is the number system digit, which indicates what type of product the symbol is identifying.
3. The third part of a UPC symbol is the manufacturer's code. This consists of five numbers (and their corresponding bars) and identifies the product manufacturer.
4. The fourth part of a UPC symbol is the centre guard pattern which consists of two thin vertical lines a bit taller than the other bars. The centre guard pattern divides the symbol in half.
5. The fifth part of a UPC symbol is the product code. This consists of five numbers (and their corresponding bars) and identifies the product.
6. The sixth part of a UPC symbol is the check digit, whose value is based on a weighting of the other digits in the code (see below).
7. The seventh part of a UPC symbol is the right guard pattern, which serves the same purpose as the left guard pattern.

The Bars

The bars in a UPC symbol consist of two bars and two spaces for each digit to be encoded. These bars and spaces fit into seven modules and are unique for each digit. The encodation of a digit in the left half of the symbol is the logical opposite of the encodation of the same digits in the right half of the symbol. All of the left digits have odd parity (the sum of the bar module widths is odd) while all of the right digits have even parity (the sum of the bar module widths is even).



The Check Digit

To prevent against errors when scanning in UPC symbols, a check digit is used. The check digit is the last digit in the UPC number, and if the computer detects an error, the UPC symbol must be scanned in again. To determine if a UPC symbol is valid, the following check procedure is used:

3 x (sum of digits in even positions) + (sum of digits in odd positions) = a multiple of 10

A UPC number has 12 digits, going from position 0 to position 11. The symbol code is in position 0 and the check digit is in position 11.

eg. 1) For the bar code at the top of this page, the symbol code is 0 and the check digit is 5.
3 x (0 + 2 + 4 + 6 + 8 + 0) + (1 + 3 + 5 + 7 + 9 + 5) = 90

eg. 2) Is the check digit in `0 63487 05148 3` correct?
3 x (0 + 3 + 8 + 0 + 1 + 8) + (6 + 4 + 7 + 5 + 4 + 3) = 89 (invalid)

eg. 3) Calculate the check digit for `0 57712 21043`.
3 x (0 + 7 + 1 + 2 + 0 + 3) + (5 + 7 + 2 + 1 + 4 + ?) = 58 + ? (check digit = 2)

Scanning

You've probably seen lots of UPC symbols been scanned in, but maybe have never thought about how the process works. This section will describe some of the basics of scanning in bar codes.

The physical device to scan in UPC symbols can vary -- sometimes it might be a fixed scanner which the product is passed by, while other times it may be a handheld scanner which is passed over the product. In either case, a beam of light is passed over the symbol, and the scanner determines the bars and spaces based on the how much of the light is reflected. (It is interesting to note that because of the way UPC symbols are designed -- the bar widths and the height of the symbol -- the scanner can determine the bars and spaces correctly even if the symbol is scanned in on a bit of an angle.)

Once the symbol has been physically read in, the reading device must process the raw data. This processing includes confirming that the code is valid and "flipping" the symbol over if the symbol was read from left to right. (The scanner would be able to determine this because of the way UPC symbols are designed -- different parities for the left and right half of the symbol.)

How UPC Bar Codes Work

by Marshall Brain

If you go look in your refrigerator or pantry right now, you will find that just about every package you see has a **UPC bar code** printed on it. In fact, nearly every item that you purchase from a grocery store, department store and mass merchandiser has a UPC bar code on it somewhere.

The bar code from a bottle of Selsun Blue dandruff shampoo

Have you ever wondered where these codes come from and what they mean? In this edition of **HowStuffWorks**, we will solve this mystery so that you can decode any UPC code you come across!

What's a UPC Bar Code?

"UPC" stands for **Universal Product Code**. UPC bar codes were originally created to help grocery stores speed up the checkout process and keep better track of inventory, but the system quickly spread to all other retail products because it was so successful.

UPCs originate with a company called the Uniform Code Council (UCC). A manufacturer applies to the UCC for permission to enter the UPC system. The manufacturer pays an annual fee for the privilege. In return, the UCC issues the manufacturer a six-digit **manufacturer identification number** and provides guidelines on how to use it. You can see the manufacturer identification number in any standard 12-digit UPC code, like this one that comes off the back of the book "The Teenager's Guide to the Real World," published by BYG Publishing:

You can see that the UPC symbol printed on a package has two parts:

- The machine-readable bar code
- The human-readable 12-digit UPC number

BYG Publishing's manufacturer identification number is the first six digits of the UPC number -- 639382. The next five digits -- 00039 -- are the **item number**. A person employed by the manufacturer, called the **UPC coordinator**, is responsible for assigning item numbers to products, making sure the same code is not used on more than one product, retiring codes as products are removed from the product line, etc. In general, every item the manufacturer sells, as well as every size package and every repackaging of the item, needs a different item code. So a 12-ounce can of Coke needs a different item number than a 16-ounce bottle of Coke, as does a 6-pack of 12-ounce cans, a 12-pack, a 24-can case, and so on. It is the job of the UPC coordinator to keep all of these numbers straight!

The last digit of the UPC code is called a **check digit**. This digit lets the scanner determine if it scanned the number correctly or not. Here is how the check digit is calculated for the other 11 digits, using the code 63938200039 from "The Teenager's Guide to the Real World" example shown above:

1. Add together the value of all of the digits in odd positions (digits 1, 3, 5, 7, 9 and 11).
   6 + 9 + 8 + 0 + 0 + 9 = 32
2. Multiply that number by 3.
   32 * 3 = 96

3. Add together the value of all of the digits in even positions (digits 2, 4, 6, 8 and 10).
   3 + 3 + 2 + 0 + 3 = 11
4. Add this sum to the value in step 2.
   96 + 11 = 107
5. Take the number in Step 4. To create the check digit, determine the number that, when added to the number in step 4, is a multiple of 10.
   107 + 3 = 110

   The check digit is therefore **3**.

Each time the scanner scans an item, it performs this calculation. If the check digit it calculates is different from the check digit it reads, the scanner knows that something went wrong and the item needs to be rescanned.

How is the Price Determined?

As you can see, there is no price information encoded in a bar code. When the scanner at the checkout line scans a product, the cash register sends the UPC number to the store's central **POS** (point of sale) computer to look up the UPC number. The central computer sends back the actual price of the item at that moment.

This approach allows the store to change the price whenever it wants, for example to reflect sale prices. If the price were encoded in the bar code, prices could never change. On the other hand, not encoding a fixed price gives the store an easy way to rip off customers. When you hear about "**scanner fraud**" in the news, that is what the newsperson is talking about. It is incredibly easy for a store to mistakenly or purposefully overprice an item.

One thing you will notice if you start looking at UPC codes in detail is that the big manufactures have manufacturer IDs with lots of zeros in them. Here are a few:

- **Post** - 043000
- **General Mills** - 016000
- **Del Monte** - 024000
- **Quaker Oats** - 030000

Here is the bar code from a 3-liter bottle of Diet Coke:

You can see that Coke's manufacturer ID is 049000. However, if you look at can of Coke or most 2-liter bottles, you will find that the UPC code is much shorter -- only eight digits total. Here's the bar code from a 2-liter bottle of Sprite:

These short bar codes are called **zero-suppressed numbers**. There's a set of rules around forming zero-suppressed numbers from full numbers, but the basic idea is to leave out a set of four digits, all zeros. In the case of the Sprite UPC code, the 049 at the beginning is the first three digits of Coke's 049000 manufacturer ID. The 551 is the item number for this bottle of Sprite, shortened from 00551. The zero in the

second-to-last digit is the fourth digit from Coke's manufacturer ID. The final digit is the normal check digit. The main reason for having zero-suppressed numbers is to create smaller bar codes for small product packages like 12-ounce cans.

The first digit of the manufacturer's identification number is special. It is called the **number system character**. The following table shows you what different number system characters mean:

0	**Standard UPC number** (must have a zero to do zero-suppressed numbers)
1	**Reserved**
2	**Random-weight items** (fruits, vegetables, meats, etc.)
3	**Pharmaceuticals**
4	**In-store marking for retailers** (A store can set up its own codes, but no other store will understand them.)
5	**Coupons**
6	**Standard UPC number**
7	**Standard UPC number**
8	**Reserved**
9	**Reserved**

Here is an example of a pharmaceutical bar code (number system character **3**), this one from a 4-ounce bottle of Selsun Blue dandruff shampoo:

Here is an example of in-store marking (number system character **4**), in this case from a $10 Toys R Us gift certificate:

Since Toys R Us is the only store that will ever use this bar code -- it's the only place where the gift certificate can be redeemed -- Toys R Us made up its own UPC code for the gift certificate and used number system **4** so it could do that.

What is a Coupon code?

The **coupon code** is interesting (number system character **5**). If you have ever wondered how the scanner can read a coupon and reject it if you haven't bought the product, here's your explanation. Here is the UPC code from a box of Post Honey Nut Shredded Wheat:

Here is the coupon for the same product:

You can see that the coupon's bar code starts with a 5 to indicate that it is a coupon. The 43000 is Post's manufacturer ID. The next three digits (186) are called the **family code**. The next two digits (70) are a **value code**. The final digit is the normal check digit.

The family code and value code are set up arbitrarily by the UPC coordinator for the manufacturer. It must be done that way because a coupon will often be usable for a whole family of products. For example, a coupon might be good for four different kinds of soap made by the same manufacturer. In the same way, the value code represents the value of the coupon arbitrarily. The manufacturer sends the retailer the data that tells the retailer's computer exactly which products fit the family code, and exactly how much to take off. When the coupon is scanned, the POS computer:

1. Decodes the family code
2. Checks to make sure the customer purchased an item from the family
3. Decodes the value code
4. Sends the discount back to the cash register

The next time you go to the store, pick up a product -- any product. Look at its UPC code: Now you know what it means!

Can I Decode the Bars?

So let's say you would like to decode the actual bars in the bar code and map them to numbers. This is something that will make you cross-eyed, but it can be done.

First of all, look at any 12-digit bar code. It is made up of black bars and white spaces between the bars. Assume that the thinnest bar or space that you see (for example, the first bar on the left) can be called "one unit wide." The bars and spaces can therefore be seen to have proportional widths of one, two, three or four units. If you look at any bar code you can see examples of these four widths.

The start of any bar code is "1-1-1." That is, starting at the left you find a one-unit-wide black bar followed by a one-unit-wide white space followed by a one-unit-wide black bar (bar-space-bar). Following the start code, the digits are encoded like this:

```
0 = 3-2-1-1
1 = 2-2-2-1
2 = 2-1-2-2
3 = 1-4-1-1
4 = 1-1-3-2
5 = 1-2-3-1
6 = 1-1-1-4
7 = 1-3-1-2
8 = 1-2-1-3
9 = 3-1-1-2
```

(Something to notice: All of these encodings seem to add up to 7.)

So let's take this barcode as an example:

The code embedded in the bars is **043000181706**:

- The bar code starts with the standard start code of 1-1-1 (bar-space-bar).
- The zero is 3-2-1-1 (space-bar-space-bar).
- The four is 1-1-3-2 (space-bar-space-bar).
- The three is 1-4-1-1 (space-bar-space-bar).
- The next three zeros are 3-2-1-1 (space-bar-space-bar).
- In the middle there is a standard 1-1-1-1-1 (space-bar-space-bar-space), which is important because it means the numbers on the right are optically inverted!
- The one is 2-2-2-1 (bar-space-bar-space).
- The eight is 1-2-1-3 (bar-space-bar-space).
- The one is 2-2-2-1 (bar-space-bar-space).
- The seven is 1-3-1-2 (bar-space-bar-space).
- The zero is 3-2-1-1 (bar-space-bar-space).
- The six is 1-1-1-4 (bar-space-bar-space).
- The stop character is a 1-1-1 (bar-space-bar).

Bar Code Activities

The following activities involve the check digit of a UPC symbol. If you don't know how the check digit works, go to the Understanding Bar Codes page.

1. For each of the following UPC symbols, determine if the UPC number is valid or not. If not, what should the check digit be?

(a) 0 66721 01259 3 (b) 0 62847 51055 4 (c) 0 56239 45280 9

(d) 0 57902 13045 8 (e) 0 68310 45277 8 (f) 0 63219 80346 6

2. For each of the following UPC symbols, calculate the check digit.

(a) 0 63211 03031 (b) 0 69052 10260 (c) 0 41771 81946

(d) 0 55773 72112 (e) 0 63936 10130 (f) 0 69848 06510

Answers to Bar Code Activity

1. (a) valid (b) invalid, 5 (c) invalid, 6 (d) valid (e) invalid, 8 (f) valid
2. (a) 0 (b) 5 (c) 0 (d) 6 (e) 2 (f) 7

Procedure for Obtaining a Barcode in Bosnia Herzegovina
Compiled by Ljiljana Dunjic, USAID LAMP
4/2004

1. Company should be registered and should have approval for work
2. Company must have identification number (IDB) - this is important for tax and custom and it proves the company is real company
3. Company must apply to EAN, placed in Chamber of Commerce BH
4. After receiving the documentation mentioned above together with invoice the procedure to get the barcode is finished
5. Each company, before receiving the barcode have one hour of education by the EAN and small brochure with basic information

Barcode numbers and prices:

- first three numbers are numbers of the state area code
- next four numbers represents identification number of the company
- other numbers are the numbers of specific products

Product numbers

1-999	company has to pay 450 KM (150 KM is membership and the rest is price for barcode numbers)
1000-5000	prices are just little bit higher than 450 KM

US Bar Code Information

I Need a U.P.C. Bar Code!

In order for your company to print U.P.C. Bar Code Symbols, your company will need to become a member of the Uniform Code Council, Inc. (UCC). When you become a member, your company will be assigned an identification number for your company's use (company prefix). You will need this number to create your own U.P.C.s

I'm not a UCC member - how do I become one?

Membership with the Uniform Code Council provides the ability to place a U.P.C. Bar Code Symbol on your product and distribute it into the marketplace. The following link leads you to the Membership Application. In addition to basic information about your company, you will be asked to provide the following facts:

- Current or projected sales revenue of your company
- The number of products that you will be identifying with a U.P.C. Symbol
- The number of locations that you might identify with a Global Location Number

This information will determine the fee that you will pay for membership. In addition, you'll be assigned a company prefix, a number that will uniquely identify your company. You will use the UCC Company Prefix provided when creating your U.P.C. Bar Code Symbol. Click here to see a short introduction to U.P.C. Bar Codes.

The Uniform Code Council is here to help. If you have questions, our Customer Service Team can be reached via the help desk at info@uc-council.org or by phone Monday-Friday, 8 a.m. to 6 p.m., EST, at 937.435.3870.

Thanks and welcome to membership with the Uniform Code Council. We look forward to serving you.

My company needs to bar code products. What do I need to do?

You can complete an application for the UCC's Partner Connections membership program, which provides you with supply chain benefits and a unique EAN.UCC Company Prefix that allows you to build bar codes.

How much is the membership fee?

The fee is determined by the number of unique products you need to identify and your company's gross sales revenue. We suggest you complete the membership application to obtain your company's membership fee. You then have the choice to continue with payment at that time or use your user ID and password to continue at a later date.

How long does it take to process my application?

Once we have received the completed application and the appropriate fee, the normal processing time is three to five business days. You will then receive a UCC Member Kit that will include a variety of valuable resources, including your licensed EAN.UCC Company Prefix.

Does the UCC provide me with bar codes?

The UCC **does not** produce bar codes. Once you receive the licensed EAN.UCC Company Prefix, you are able to assign your Item Reference Numbers with resources provided in the UCC Member Kit. You can then have the bar codes produced by a printer that has bar coding software or print bar codes yourself. A listing of Solution Providers can be obtained at:

http://usnet03.uc-council.org/sp_dir_new/listing.cfm .

How do I assign my bar code numbers (Item Reference Numbers)?

Using your licensed EAN.UCC Company Prefix, each product is defined by a unique set of numbers, referred to as the Item Reference Number. For instructions, please refer to:

http://www.uc-council.org/ean_ucc_system/membership/create_number.htm

Do I need to register my products with UCC?

No, the Item Reference Numbers that you or your manufacturers assign are maintained within your company. They are not registered with the UCC. You will need to communicate this information to your trading partners only.

If I need additional information on membership, who can I contact?You can call the UCC's Partner Connections team Monday thru Friday 8 a.m. to 6 p.m. EST at 937-435-3870. You can also contact them via email at info@uc-council.org .

Partner Connections, the UCC's Membership Program
Your Link to Exclusive Supply Chain Resources

Membership Page Links
I Need a U.P.C. Bar Code
Partner Connections Membership FAQ's
Company Profile Form
Industry Initiatives

Partner Connections can help your company meet the technology standards and specifications of the world's largest retailers, manufacturers, distributors, wholesalers, and end-users. Your membership provides unlimited access to important benefits, including business resources, a unique company prefix to build bar codes, implementation guidelines for standards, essential industry news about your trading partners, and research to help you drive your business success.

These Partner Connections benefits help your business meet your partners' supply chain requirements, generate additional revenue, and reduce your overall supply chain costs:

- **Guidelines and Tools** – Drive business efficiency with unlimited access to the UCC Solutions Center®, the UCC's repository for standards and guidelines. This online library and resource center – the world's leading information source on supply chain standards – includes thousands of pages of helpful information. It's an easy-to-navigate site that includes everything from the basic steps for building a U.P.C. bar code to highly detailed guidelines for implementing Electronic Data Interchange (EDI).
- **Web Seminars** – The ultimate training in supply chain standards, delivered right to your desk, at no extra cost. Get a better understanding of how to implement UCC standards. These presentations deliver critical education topics in a timesaving, easily accessible format. Topics include Bar Code Basics, Preparing for 2005 Sunrise, Barriers to Global Trade Item Numbers (GTINs) and How to Overcome Them, and Understanding Extensible Markup Language (XML).
- **Discounts on UCC Products, Services, and Educational Events** – Enjoy discounts on printed and electronic resources that can assist your company in using identification standards and electronic commerce. Partner Connections members also save on registration fees for the annual U Connect Conference, the industry's leading education and networking event.
- **Exclusive Business Information** – Essential information, industry trends, and best practices brought to you in our quarterly email newsletter, *UCC: Between the Lines.*
- **Extensive Research and Partner Connections Support** – Our Partner Connections Team can help you with extensive supply chain research, information and implementation guidance. Partner Connections customer service representatives have immediate access to UCC and other industry professionals to answer difficult or complicated questions to help ensure that your business has the most current information about innovative and effective supply chain tools.
- **A Unique Company Prefix** – A unique number will be assigned and reserved just for use by your company. Use this company prefix to create identification numbers to build bar codes and other data carriers. Your company prefix will also be listed in the UCC Membership Directory that is provided to retailers and distributors.

Meet the technology standards and specifications of the world's largest retailers, manufacturers, distributors, wholesalers, and end-users.

Join Partner Connections today.
Your Link to Exclusive Supply Chain Resources

Partner Connections is a program of the Uniform Code Council and is subject to change.

Click here for Browser Requirements

UCC Membership Application

All applicants are requested to enter all of their membership information here in the UCC Online Membership Application whether they choose to pay the membership fee online using our secure site, with VISA, MasterCard, or AMEX or mail the payment to the UCC P.O. Box Address. The UCC is utilizing the services of Verisign CyberCash for the secure credit card payment transactions.

Directions & Help

For detailed information and help, please use the UCC Online Help. To access the UCC Online Help, follow the **help** icon located at the top portion of this form.

Have a question about the membership? Visit our Membership Frequently Asked Questions Page at **FAQ page**.

How to Apply:

The membership fee is determined by the information you provide about your company on the on-line application. Two of the key factors that are considered are current total U.S. annual gross sales revenue and numbering capacity needs.

Application Processing: Allow up to 5 business days (from the date the UCC receives your completed application and payment) for the processing of your application. This does not include shipping time.

To submit through the Internet: Complete this application and include your credit card information when submitting it.

To submit by Fax or Email: Complete this application and select the appropriate option when presented.

To submit by Mail: Complete this application and select the appropriate option when presented.

Reference >> Packaging Terminology

The following definitions apply in this Standard.

Ampoule — A small glass vessel in which liquids for injections are hermetically sealed.

Bag-in-box — A package comprising a carton containing a bag which closely fits the carton and contains the product.

Bead seal — A seal in which the two edges of the material are welded together along a very narrow strip without overlap.

Blister — A thermoformed clear plastic shape which is used to make a blister pack.

Blister pack — A package which usually comprises a clear plastic shape containing a product, which is heat sealed to a backing card.

Block bottom bag — A flexible package with a tucked and sealed base which allows the filled and sealed pack to stand on its base.

Capsule — A secondary seal placed over a primary closure, typically used on wine bottles.

Carton — A container which is made from carton board, generally between 0.25mm and 1.0mm in thickness, and is usually delivered to the user in the form of a carton blank.

Carton blank — An individual carton in the flat after cutting and creasing and with the strippings removed.

Carton board — A material made from one or more layers of fibrous cellulose material to form a rigid or semi-rigid construction, generally 0.25mm to 1.0mm thick.

Carton tray — A rectangular open carton with sides and ends made from carton board generally between 0.25mm and 1.0mm in thickness and usually delivered to the user in the form of a carton blank.

Closure — A packaging component used to close a container or package.

Collapsible tube — A container for pastes, usually made from a malleable metal or plastic.

Corrugated board — A material comprising one or more sheets of fluted paper stuck between flat sheets of paper.

Crimping — Mechanical deformation of a deformable material, usually a metal.

Crown closure — A metal closure containing a sealing wad, which is crimped to the neck of a bottle.

Cup — A thin walled tapered plastic pot, usually with height greater than its diameter.

Deformable material — A material which can be formed by the application of pressure only.

Film reel — A continuous sheet of paper, carton board, plastics film, metal foil or flexible laminate wound on a cylindrical core.

Film web — A continuous sheet of paper, plastics film, metal foil or laminate.

Fin seal — A seal in which the two edges of the material are joined together inner surface to inner surface.

Flexible packaging film — A continuous sheet of paper, plastics film, metal foil or laminate.

Group package — An assembly of products prepared for transit, including cases, crates, trays, shrinkwrap packs, bundles and multipacks.

Gusset — The inwardly folded portion of a flexible package, usually a bag or sack.

Layer pad — A sheet of card or corrugated board used to stabilise a pallet or loading unit.

Lay flat tubular film — A continuous tube of plastic film usually supplied wound on a core.

Loading unit — Generally a palletised load, but including assemblies of group packages which are not on pallets.

Longitudinal seal — A seal made on a package in line with the direction of material travel in the machine.

Magazine — A mechanical assembly designed to hold stacks of cartons, carton blanks, leaflets, labels, lids or stackable containers.

Mandrel — A mechanical assembly around which a bag or carton is formed.

Overlap seal — A seal in which the two edges of the material are joined together inner surface to outer surface.

Package — A term embracing all types of packages e.g. bottles, cans, cartons, bags etc.

Packaging material transport mechanism — A mechanical assembly which transports packaging material through the Packaging Machine.

Paper laminate — Paper that has been coated or bonded to one or a number of other materials e.g. polyethylene or aluminium foil.

Pre-made bag — A pre-formed flat or gusseted flexible container longitudinally seamed and closed at one end made from paper, plastics film, foil, laminate or a woven material etc.

Pre-made sack — A pre-formed flat or gusseted sack longitudinally seamed and closed at one or both ends made from paper, plastic film, laminate, or a woven material etc.

Rigid container — A term embracing bottles, jars, drums, barrels, kegs, pails, cups, tubs, ampoules, vials, cans and composite cans.

Roll-on closure — A straight-sided aluminium closure which is rolled over the neck of a bottle to form the screw thread.

Sachet — A flat package which when formed from two webs of flexible material is sealed on four sides and when formed from one web is sealed on three or four sides.

Scroll — A mechanism used to separate and accurately position rigid containers, usually comprising a solid plastic cylinder with a helical groove cut in it to accept the containers.

Shrinkwrapping — A process in which a package is wrapped in a thermoplastic film which is then heated so that the film shrinks to closely fit the package.

Star wheel — A mechanism used to accurately position rigid containers, usually comprising a solid plastic wheel with machine pockets to accept the containers.

Side seam seal — The longitudinal seal which is made by stitching, heatsealing or applying adhesive, when a carton blank is formed into a flat carton.

Stretchwrapping — A process in which a package is wrapped in a thermoplastic film which is pulled tightly around the package. The film may be formulated to stick to itself on contact.

Tear tape — A plastic tape which is sealed to a packaging material, usually plastic film, to assist opening of the pack.

Thermoformable material — A material which when heated can be formed by pressure and/or vacuum.

Thermoplastic film — A plastic film which shrinks when heated.

Top load carton — A one piece carton which is erected by first interlocking or gluing the side members to the body part and having a lid with side flaps which can either be tucked or glued to the carton body to close the carton.

Transverse seal — A seal made on a package at right angles to the direction of

material travel in the machine.

Tub — A thin walled tapered plastic pot, usually with height less than its diameter.

Vial — A small bottle for liquids.

Reference >> Packaging Machine Definitions

1.0 Filling Machines

Packaging machines which measure out a product from bulk by some

1.1 Volumetric filling machines

1.1.1 Volumetric cup filling machine — A filling machine which

1.1.2 Displacement filling machine — A filling machine which

1.1.3 Volumetric piston filling machine — A filling machine which

1.1.4 Rotating chamber filling machine — A filling machine which

1.1.5 Flow meter filling machine — A filling machine which measures

1.1.6 Auger filling machine — A filling machine which measures out a

1.2 Level filling machines

1.2.1 Vacuum filling machine — A filling machine which fills a product

1.2.2 Gravity filling machine — A filling machine which fills a product,

product flowing under gravity.

1.2.3 Pressure filling machine — A filling machine which fills a product, usually liquid, to a predetermined level in a rigid container, with product under pressure.

1.3 Timed flow filling machines

Filling machines which measure out a product, usually a liquid or powder, by controlling the product flow duration to a predetermined value.

1.4 Gravimetric filling machines

1.4.1 Nett weighing machine — A filling machine which measures out a predetermined mass of product, usually free-flowing solids, before dispensing it as a fill.

1.4.1.1 Selective combination weighing machine — A nett weighing machine with multiple weighing units, which computes an appropriate combination of loads to achieve the predetermined mass and discharges them together as a fill.

1.4.2 Gross weighing machine — A filling machine which measures out a predetermined mass of product, which may be liquid, powder, gas or solids, directly into the package, while it rests on a weighing instrument which controls the filling operation.

1.5 Count filling machines

Filling machines which measure out solids according to a predetermined count.

2.0 Closing Machines

Packaging machines which seal or close filled packages.

2.1 Closing machines which do not use a closure or closing material

2.1.1 Fold closing machine — A closing machine which seals a package, usually a bag or collapsible tube, by folding.

2.1.2 Tuck closing machine — A closing machine which closes a package, usually a carton, by engaging pre-cut tabs and slots. See also 9.2.1.

2.1.3 Crimp closing machine — A closing machine which closes a package, usually a bag or collapsible tube, by crimping.

2.1.4 Weld sealing machine — A sealing machine which seals a package, usually metal, by welding.

package, usually metal, by welding.

2.1.5 Fusion sealing machine — A sealing machine which seals a package, usually glass, by fusion welding.

2.1.6 Solder sealing machine — A sealing machine which seals a package, usually metal, by soldering.

2.1.7 Heat sealing machine — A sealing machine which seals a package, usually plastic, by heat sealing.

2.1.7.1 Blister sealing machine — A sealing machine which seals a filled plastic blister to a piece of coated cartonboard, by the application of heat.

2.1.8 Induction sealing machine — A sealing machine which seals a foil laminate lid to a container in a electromagnetic field.

2.2 Closing machines which use a closure

2.2.1 Screw capping machine — A closing machine which applies a threaded cap or lid, usually to a rigid container.

2.2.1.1 Steam capping machine — A closing machine which sterilises the cap and filled rigid container with steam during the closing process.

2.2.3 Plugging; corking machine — A closing machine which pushes a plug or cork into the mouth of a rigid container.

2.2.4 Press-on lidding machine — A closing machine which pushes a lid, usually metal, plastic or other material, on to a rigid container.

2.2.5 Crown capping machine — A closing machine which places a pre-formed metal cap over the mouth of a rigid container, before crimping the edges of the cap to secure it to the container.

2.2.6 Roll-on capping machine — A closing machine which places a deformable capsule over the mouth of a rigid container, before rolling the capsule to form a thread and secure the capsule to the container.

2.2.7 Can seaming machine — A closing machine which places a pre-formed lid onto the mouth of a can, before rolling the edges of the lid and can together to form a seal.

2.2.8 Cork wiring machine — A closing machine which applies a wire cage to the neck and cork of a rigid container, to prevent the cork being pushed out by gas pressure in the container.

2.2.9 Aerosol valve closing machine — A closing machine which places an aerosol valve into the mouth of a rigid container before seaming the valve to the container.

seaming the valve to the container.

2.2.10 Pump applicator — A closing machine which places a dispensing pump into the mouth of a rigid container before attaching the pump to the container.

2.3 Closing machines which use a closing material

2.3.1 Staple closing machine — A closing machine which closes packages, usually corrugated cases, with metal staples. See also 11.3.3.

2.3.2 Nail closing machine — A closing machine which closes packages, usually wooden boxes, with nails.

2.3.3 Rivet closing machine — A closing machine which closes packages, usually metal, with rivets.

2.3.4 Clip closing machine — A closing machine which closes packages, usually rigid containers, with metal clips.

2.3.5 Sewing machine — A closing machine which closes packages, usually paper sacks, by sewing.

2.3.6 Glue sealing machine — A sealing machine which seals packages, usually bags, cartons or corrugated board cases, with an adhesive. See also 11.3.1.

2.3.7 Gummed tape sealing machine — A sealing machine which seals packages, usually corrugated board cases, with gummed tape. See also 11.3.2.2.

2.3.8 Tape sealing machine — A sealing machine which seals packages, usually corrugated board cases, with pressure sensitive tape. See also 11.3.2.1.

2.3.9 Strapping machine — A sealing machine which seals packages with a metal or plastic strap.

2.3.10 Twist-tie closing machine — A closing machine which closes packages, usually bags, by twisting a wire closure around the neck of the package.

2.3.11 Foil sealing machine — A packaging machine which applies a reel fed foil or plastic cover to a rigid container, which is usually plastic.

3.0 Labeling, Decorating and Marking Machines

Packaging machines which apply labels, decoration or codes and other markings to packages.

3.1 Labeling machines

3.1.1 Wet glue labeling machine — A labeling machine which applies labels, usually to a rigid container, using an adhesive which is liquid at room temperature.

3.1.2 Hot melt glue labeling machine — A labeling machine which applies labels, usually to a rigid container, using an adhesive which is solid at room temperature.

3.1.3 Pressure sensitive labeling machine — A labeling machine which applies pre-glued labels, which are supplied on a reel of release paper or film.

3.1.4 Heat seal labeling machine — A labeling machine which applies labels coated with a heat sealable material.

3.1.5 Pre-gummed label applicator — A labeling machine which applies pre-gummed labels to packages.

3.1.6 Print and apply labeling machine — A labeling machine on which a label is first printed and then applied to a package.

3.1.7 Weigh price labeling machine — See 6.1.1.2.

3.2 Decorating machines

3.2.1 Tag labeling machine — A packaging machine which applies a tag, usually to a rigid container, either by placing it over the neck of the container, or by fixing it to the container with glue.

3.2.2 Foiling machine — A packaging machine which applies a decorative foil to the neck of a closed rigid container.

3.2.3 Shrink sleeving machine — A packaging machine which places a tube of plain or printed thermoplastic material over the neck of a rigid container, before heat shrinking it so that it closely fits the container.

3.2.4 Capsuling machine — A packaging machine which applies a decorative capsule to the neck of a rigid container.

3.3 Marking machines

3.3.1 Emboss coder — A machine attachment which marks a package by embossing or debossing with raised type.

3.3.2 Wet ink coder — A machine attachment which marks a package by printing it with wet ink.

3.3.3 Hot foil coder — A machine attachment which marks a package by transferring dry ink, carried on a reel of film, with a heated die.

transferring dry ink, carried on a reel of film, with a heated die.

3.3.4 Solid ink coder — A machine attachment which marks a package by transferring dry ink from a solid block, with a heated die.

3.3.5 Ink jet coder — A machine attachment which marks a package by jetting ink in a predetermined pattern.

3.3.5.1 Drop-on-demand ink jet coder — An ink jet coder which prints a character by jetting ink from a matrix of nozzles.

3.3.5.2 Continuous stream ink jet coder — An ink jet coder which prints a character by applying varying electrostatic charges to droplets of ink.

3.3.6 Laser coder — A machine attachment which marks a package with a laser.

4.0 Cleaning, Sterilizing, Cooling and Drying Machines

Machines which clean, sterilise, cool or dry containers or filled packages.

4.1 Cleaning machines

4.1.1 Air cleaning machine — A packaging machine which cleans the inside of rigid containers by injecting a gas, usually air, into the inverted containers.

4.1.2 Rinsing machine — A packaging machine which cleans the inside of a rigid container by injecting a liquid, usually water, into the inverted container.

4.1.3 Bottle washing machine — A packaging machine which cleans the inside and outside of rigid containers, usually with water and detergent.

4.1.4 Crate washing machine — A packaging machine which cleans crates, usually with water and detergent.

4.2 Sterilising machines

4.2.1 Container sterilising machine — A packaging machine which sterilises empty rigid containers, before they are filled.

4.2.2 Continuous steriliser — A packaging machine which sterilises packaged products by heating and then cooling them continuously under controlled conditions.

4.2.3 Batch steriliser — A packaging machine which sterilises packaged products by heating and then cooling them under controlled conditions in a batch process.

a batch process.

4.3 Pasteurising machines

4.3.1 Continuous pasteuriser — A packaging machine which pasteurises packaged products by heating and then cooling them continuously under controlled conditions.

4.3.2 Batch pasteuriser — A packaging machine which pasteurises packaged products by heating and then cooling them under controlled conditions in a batch process.

4.4 Cooling, warming and drying machines

4.4.1 Cooling machine — A packaging machine which reduces the temperature of empty or filled and sealed packages.

4.4.2 Drying machine — A packaging machine which removes surface moisture from empty containers or filled sealed packages.

4.4.3 Warming machine — A packaging machine which warms empty glass containers before they are hot filled.

5.0 Fill and Seal Machines

Packaging machines which combine the functions of filling and closing in one machine.

5.1 Rigid container fill and close machines

5.1.1 Ampoule/vial fill and close machine — A packaging machine in which glass ampoules or vials are first filled with a liquid (1.2.2) and then fusion sealed (2.1.5).

5.1.2 Bottle fill and cap machine — A packaging machine in which bottles are first filled with a liquid and then capped (2.2.1).

5.1.3 Can fill and seam machine — A packaging machine in which cans are first filled and then seamed (2.2.7).**5.1.4 Cask or keg fill and seal machine** — A packaging machine in which casks or kegs are first filled and then sealed.

5.2 Flexible package fill and seal machines

5.2.1 Bag fill and seal machine — A packaging machine in which a pre-made bag is taken from a magazine, opened, filled with product and then sealed.

5.2.1.1 Reel fed bag fill and seal machine — A packaging machine in which a bag is separated from a reel of pre-made bags, before being opened, filled with product and then sealed.

opened, filled with product and then sealed.

5.2.2 Sack fill and close machine — A packaging machine in which a pre-made sack is taken from a magazine, before being opened, filled with product and then closed.

5.2.3 Tube fill and seal machine — A packaging machine in which collapsible tubes are taken from a magazine, filled (1.1.3) and then fold, crimp or heat sealed (2.1.1, 2.1.3 or 2.1.7).

5.2.4 Cup/tub fill and seal machine — A packaging machine in which a plastic cup or tub is taken from a magazine, filled and then closed with a heat sealed foil (2.3.11) and/or a press-on lid (2.2.4).

5.2.5 Blister fill and seal machine — A packaging machine in which a pre-formed plastic blister is taken from a magazine, filled with product and then sealed to a backing card.

6.0 Inspection Machines

Packaging machines which inspect products, packages or packaging components, for a particular attribute, e.g. colour, size, mass, and reject items which fall outside pre-set values.

6.1 Inspection machines for products

6.1.1 Checkweigher — A measuring instrument which measures the mass of a package or product, usually as it travels on a conveyor, records the mass of the item and rejects and that fall outside pre-set values.

6.1.1.1 Weight classifying machine — A checkweigher which divides products into groups according to their mass.

6.1.1.2 Weigh price labeling machine — A checkweigher which weighs filled packages, calculates the selling price, prints a label with the mass and price and then applies the label to the package.

6.1.2 Fill height inspection machine — A packaging machine which detects the level of fill in a container, and rejects containers which fall outside pre-set values.

6.1.3 Foreign body detecting machine — An inspection machine which detects the presence of foreign bodies in a product, and rejects them.

6.1.3.1 Metal detecting machine — An inspection machine which detects thepresence of metal in products and rejects the product or the packaging in which it is contained.

6.2 Inspection machines for packages

6.2.1 Aerosol testing machine — A inspection machine which checks filled aerosol cans for leaks.

6.2.2 Cap inspecting machine — A inspection machine which inspects filled and closed rigid containers for the presence of a cap, and rejects containers without caps.

6.2.3 Empty bottle inspection machine — A packaging machine which inspects empty bottles for some attribute, e.g. size, wall thickness, cleanliness, and rejects bottles which fall outside pre-set values.

6.2.4 Label inspecting machine — An inspection machine which detects labels on packages and checks that they comply with pre-set requirements e.g.orientation, print quality, alignment.

6.2.5 Open flap detector — An inspection machine which detects the presence of an open flap on a carton or case and rejects them.

6.2.6 Seal checking machine — An inspection machine which tests the integrity of package seals and rejects faulty packages.

7.0 Container and Component Handling Machines

Packaging machines which arrange, dispense or accumulate packages or packaging components.

7.1 Arranging machines

7.1.1 Rigid container unscrambler — A packaging machine which accepts a bulk supply of randomly oriented containers, usually plastic bottles, and dispenses the containers in a predetermined orientation.

7.1.2 Component unscrambler — A packaging machine which accepts a bulk supply of packaging components e.g. caps, and dispenses them in a predetermined orientation.

7.1.3 Rigid container single liner — A packaging machine which accepts a bulk flow of rigid containers and reduces them to a single line of containers.

7.1.4 Rigid container orienter — A packaging machine which accepts a line of rigid containers with random rotary orientation, and dispenses them with the same rotary orientation.

7.2 Dispensing machines

7.2.1 Rigid container denester — A packaging machine which dispenses rigid containers, usually cups, tubs or trays, from a stack or magazine. See also 11.5.

magazine. See also 11.5.

7.2.2 Leaflet feeder — A packaging machine or attachment which dispenses a leaflet, card or coupon from a stack or magazine.

7.2.3 Bag presenting machine — A packaging machine which removes a pre-made bag from a magazine and opens it ready for filling.

7.2.3.1 Sack presenting machine — A packaging machine which removes a pre-made sack from a magazine and opens it ready for filling.

7.2.4 Sack seal and present machine — A packaging machine which from a reel of tubular film, forms the base of a sack by heat sealing, separates the sack from the reel and opens it ready for filling.

7.2.5 Straw applicator — A packaging machine attachment which applies a pre-wrapped straw to a package.

7.2.6 Tear tape applicator — A packaging machine attachment which applies a strip of tear tape to film, usually on a wrapping machine.

7.2.7 Handle applicator — A packaging machine or packaging machine attachment which applies a handle to a package.

7.2.8 Spoon applicator — A packaging machine attachment which applies a spoon to a package.

7.2.9 Key applicator — A packaging machine which attaches an opening key to a package.

7.2.10 Pallet dispenser — See 12.4.1.

7.2.11 Layer pad dispenser — See 12.4.4.

7.2.12 Top sheet dispensing machine — See 12.4.6.

8.0 Form, Fill and Seal Machines

Packaging machines which form, fill and seal a package in the same machine.

8.1 Horizontal form, fill and seal machines

Packaging machines which use flexible packaging film, to form a package which is then filled and sealed in a sequence of operations while the film is being transported in a horizontal direction.

8.1.1 Flowrapping machine — A horizontal form, fill and seal machine with film reel mounted above the operating level, the product loaded horizontally and a longitudinal seal formed below the pack.

8.1.2 Lower reel flowrapping machine — A horizontal form, fill and seal machine, with film reel mounted below the operating level, product placed on to the film web and a longitudinal seal formed above the pack.

8.1.3 Edge sealing machine — A horizontal form, fill and seal machine in which product is placed on a horizontal web of film before being sealed on 3 or 4 sides to an upper web of film. Machines can have one or two reels of film and can produce one or more lanes of packs.

8.1.4 Sachet form, fill and seal machine — A horizontal form, fill and seal machine in which packs are formed, sealed on 2 or 3 sides, filled vertically with product and sealed on the remaining side whilst the film web is moved horizontally with the pack vertical.

8.2 Vertical form, fill and seal machines

Packaging machines which use flexible packaging film to form a tube, which is then filled vertically with product and sealed in a sequence of operations whilst the film is transported vertically downwards.

8.2.1 Vertical form, fill and seal machine for cartons — A vertical form fill and seal machine which uses a heavy paper laminate, which isformed, filled with product, usually a liquid and sealed to produce a pack resembling a carton.

8.2.2 Vertical sachet form, fill and seal machine — A vertical form, fill and seal machine which uses one or two webs of film which are formed vertically, filled with product and sealed to produce a 3 or 4 side sealed sachet. Machines can have one or two reels of film and can produce one or more lanes of packs.

8.2.3 Strip packing machine — A vertical sachet form, fill and seal machine which produces strips of individually sealed packs joined together in predetermined lengths.

8.3 Tubular bag form, fill and seal machines

Packaging machines which form a bag from a reel of lay flat tubular flexible packaging film. The bag is then filled with product and sealed within the machine.

8.4 Mandrel flexible package form, fill and seal machines

Packaging machines which form packs from a reel of flexible material, on one or a number of mandrels, before filling the packs with product and sealing their tops within the machine.

8.5 Deep draw form, fill and seal machines

8.5.1 Cold form, fill and seal machine — A form, fill and seal machine in which a web of deformable material is formed under pressure in a die press, before being filled vertically with product sealed, with a top film or magazine fed lid, and finally cut to produce individual packs. Machines can produce one or more lanes of packs.

8.5.2 Thermoform, fill and seal machine — A form, fill and seal machine in which a web of thermoformable material is heated and formed with pressure and/or vacuum, before being filled vertically with product, sealed with a top film or magazine fed lid and finally cut to produce individual packs. Machines can produce one or more lanes of packs and may incorporate equipment to evacuate packages before they are sealed.

8.6 Blow mould fill and seal machines

Packaging machines in which plastic granules are melted, extruded, blow moulded to form a container, filled with product and sealed within the machine.

8.7 Carton form, fill and seal machines

See 9.3.

8.8 Group package form, fill and seal machines

See 11.4.

9.0 Cartoning Machines

Packaging machines which erect, close or erect fill and close carton blanks or folded and side seam sealed cartons.

9.1 Carton erecting machines

9.1.1 Carton blank erecting machine — A packaging machine which forms cartonboard blanks into cartons and secures them by engaging pre-cut tabs and slots, by applying adhesive or by applying heat to pre-coated board.

9.1.2 Skillet erecting machine — A packaging machine which erects pre-glued cartonboard skillets and secures them by engaging pre-cut tabs and slots, by applying adhesive or by applying heat to pre-coated board.

9.2 Carton closing machines

9.2.1 End flap carton closing machine — A packaging machine which closes cartons and secures them by engaging pre-cut tabs and slots, by applying adhesive or by applying heat to pre-coated board.

applying adhesive or by applying heat to pre-coated board.

9.2.2 Three flap carton closing machine — A packaging machine which closes 3 flap cartons and secures them with adhesive or by the application of heat to pre-coated board.

9.3 Carton form, fill and seal machines

9.3.1 Mandrel carton form, fill and seal machine — A cartoning machine which forms cartons either from magazine fed or reel fed carton blanks, around one or a number or mandrels, before filling the cartons with product and closing them in the machine.

9.3.2 Mandrel bag-in-box machine — A cartoning machine which forms a bag , made from a reel of flexible material on a mandrel, around which a carton blank is formed to produce a bag-in-box package. This package is then filled with product before first the bag and then the carton are closed.

9.3.3 Horizontal end load cartoner — A cartoning machine which erects a folded and side seam sealed carton and places it on a horizontal indexing mechanism so that the carton can be filled with product horizontally through an end flap of the carton before being closed.

9.3.4 Vertical cartoner — A cartoning machine which erects a folded and side seam sealed carton and places it on a horizontal indexing mechanism so that the carton can be filled with product vertically through the carton top flap before being closed.

9.3.4.1 Pre-made bag-in-box cartoner — A vertical cartoner which erects side seam sealed and folded cartons which contain a tube of flexible film. The base of the tube is sealed before it is filled vertically with product. After filling the top of the tube is sealed before the carton flaps are closed.

9.3.4.2 Reel fed bag-in-box cartoner — A vertical cartoner which erects a side seam sealed and folded carton before forming a bag from a reel of flexible film and placing it in the carton. The bag is filled vertically with product before the top of the bag is sealed and the carton flaps are closed.

9.3.5 Tray erect load and seal machine — A cartoning machine in which a carton tray blank is partly formed before being loaded horizontally with product. After loading the carton tray is fully formed and sealed within the machine.

9.3.6 Top load carton form, fill and seal machine — A cartoning machine in which a carton blank is partly formed into an open top carton before being loaded vertically with product. After loading the carton is fully formed and closed within the machine.

before being loaded vertically with product. After loading the carton is fully formed and closed within the machine.

9.3.7 Wraparound cartoner — A cartoning machine which wraps a cartonboard blank around a product, usually with the aid of a mandrel, before closing the carton with adhesive or by tucking.

9.3.8 Wraparound sleeving machine — A cartoning machine which wraps a cartonboard blank around a product, or group of products, securing it by engaging pre-cut tabs and slots or by the application of adhesive.

10.0 Wrapping Machines

Packaging machines which wrap a flexible packaging material e.g. paper, aluminium, plastic film, around a product or groups of products.

10.1 Wrapping machines which partially wrap products

10.1.1 Banding machine — A wrapping machine which wraps a band of material around a product or group of products and secures it with adhesive or by the application of heat.

10.1.2 Sleeve wrapping machine — A wrapping machine which wraps a band of thermoplastic material loosely around a product or group of products, before the pack is passed through a shrink tunnel to form a shrink-wrap pack. The band may be formed from one or two reels of film.

10.1.3 Stretch banding machine — A wrapping machine which wraps a band of thermoplastic film tightly around a product or group of products.

10.1.4 Spiral wrapping machine — A wrapping machine which wraps a web of thermoplastic tightly around a product or group of products, in a series of turns while the product is conveyed through the machine.

10.2 Wrapping machines which form a complete wrap without sealing

10.2.1 Fold wrapping machine — A wrapping machine which wraps a product in a deformable material e.g. aluminium foil or paper, in a series of folding operations.

10.2.1.1 Edible fat/butter wrapping machine — A fold wrapping machine in which butter or edible fat is extruded, cut to size and then wrapped in a deformable material.

10.2.2 Twist wrapping machine — A wrapping machine which seals the open ends of the wrap by twisting.

10.3 Wrapping machines which form a complete wrap with sealing

10.3.1 Overwrapping machine — A wrapping machine which wraps a product or group of products in flexible packaging material with a series of folding, heat sealing or gluing operations.

10.3.2 Roll wrapping machine — A wrapping machine which wraps a cylindrical product or group of products, in a series of folding, heat sealing or gluing operations, to form a roll shaped pack.

10.3.3 Foil and band wrapping machine — A wrapping machine which wraps a product in aluminium foil, before applying a paper band to complete the pack.

10.3.4 Pleat wrapping machine — A wrapping machine which gathers and folds flexible material around a product and seals it at one point by applying a label.

10.3.5 Stretch film wrapping machine — A wrapping machine which pulls a web of stretch film around a product, before gathering and heat sealing the film edges below the product.

10.3.6 L-sealing machine — A wrapping machine which uses thermoplastic film folded in half along its length. Products or groups of products are placed between the two halves of film, before the film is sealed around the product with an L shaped sealing bar, to produce a fully enclosed pack, sealed on three sides.

10.3.7 Flowrapping machine — see 8.1.1.

10.3.8 Edge sealing machine — see 8.1.3.

10.4 Skin packing machines

Wrapping machines which seal products placed on perforated and coated cartonboard blanks, with a web of thermoplastic film.

10.5 Shrinking equipment

10.5.1 Shrink tunnel — A machine which shrinks thermoplastic film around a product or group of products, as they pass through a heated tunnel. The heating medium may be hot air, radiant heat or steam.

10.5.2 Shrink oven — A machine which shrinks thermoplastic film around a product or group of products, in a heated chamber.

10.5.3 Shrink frame — A machine which shrinks thermoplastic film around a product or group of products, as it is moved over the surface of the product.

the product.

10.6 Wrapping machines for loading units

See 12.3.

11.0 Group or Transit Packaging Machines

Packaging machines which group together a collation of products for transit purposes. Group packages include cases, trays, crates and cartonboard sleeves.

11.1 Group container erecting machines

11.1.1 Tray erecting machine — A packaging machine which erects trays, usually from pre-cut corrugated board blanks.

11.1.2 Case erecting machine — A packaging machine which erects side seamed cases, usually made from corrugated board.

11.1.3 Division inserting machine — A packaging machine which assembles and places pre-cut divisions into a group package, usually a corrugated board case.

11.2 Group container loading/unloading machines

11.2.1 Drop packing machine — A packaging machine which assembles groups of products and loads them into group packages by gravity.

11.2.2 Place packing/unpacking machine — A packaging machine which grips groups of products and either places them vertically into or removes them from group packages.

11.2.3 Horizontal packing machine — A packaging machine which assembles groups of packages and loads them horizontally into group packages, usually corrugated board cases.

11.3 Group container sealing machines

11.3.1 Case gluing machine — A packaging machine which closes cases, usually made from corrugated board, and seals them with adhesive.

11.3.2 Case tapers

11.3.2.1 Pressure sensitive tape sealing machine — A packaging machine which closes cases, usually made from corrugated board, and seals them with self-adhesive tape.

11.3.2.2 Pre-gummed tape sealing machine — A packaging machine which closes cases, usually made from corrugated board, and seals them with gummed tape.

11.3.3 Case stapling machine — A packaging machine which closes cases, usually made from corrugated board, and seals them with staples.

11.3.4 Wraparound lidding machine — A packaging machine which closes group packages, usually deep wall trays, by folding a corrugated board blank around the open top of the pack and securing it with adhesive.

11.4 Group package form, fill and seal machines

11.4.1 Plastic ringing machine — A packaging machine which groups rigid containers and holds them together with pre-cut plastic, supplied to the machine in reel form.

11.4.2 Wraparound traypacking machine — A packaging machine which groups packages together and wraps a pre-cut tray blank around them.

11.4.3 Wraparound casepacking machine — A packaging machine which groups packages together and wraps a pre-cut case blank around them.

11.4.4 End load casepacking machine — A packaging machine which groups packages together and loads them horizontally into side seamed cases which are closed within the machine.

11.4.5 Top load casepacking machine — A packaging machine which groups packages together and loads them vertically through the top of side seamed cases which are closed within the machine.

11.4.6 Bottom load casepacking machine — A packaging machine which groups packages together and loads them vertically through the bottom of side seamed cases which are closed within the machine.

11.4.7 Wraparound sleeving machine — See 9.3.8.

11.5 Group package handling machines

11.5.1 Tray denesting machine — A packaging machine which dispenses trays, usually plastic or fibre board, from a stack.

11.5.2 Crate stacking/unstacking machine — A packaging machine which stacks or unstacks crates, which may be full or empty.

11.5.3 Tray stacker — A packaging machine which stacks trays, which are usually filled.

11.6 Group package wrapping machines

See section 10.0.

12.0 Pallet Forming, Dismantling and Securing Machines

Packaging machines which form, dismantle or secure pallets and other loading units.

12.1 Pallet forming machines

12.1.1 Low level palletizer — A packaging machine which forms a loading unit, usually comprising group packages, which are fed to the machine at low level.

12.1.2 High level palletizer — A packaging machine which forms a loading unit, usually comprising group packages, which are fed to the machine at high level.

12.1.3 Multi-position palletizer — A packaging machine which forms a number of different loading units simultaneously. Group packages are formed into layers and transferred to the appropriate pallet, a layer at a time.

12.1.4 Robot palletizer — A packaging machine which forms a loading unit, usually comprising group packages, which are picked up, oriented and placed on the pallet one at a time.

12.1.5 Lift-off palletizer — A packaging machine which forms a loading unit, usually comprising rigid containers or group packages, which are formed into layers and then lifted, a layer at a time, and placed on the pallet.

12.2 Pallet dismantling machines

12.2.1 Lift-off depalletizer — A packaging machine which dismantles a loading unit, usually comprising rigid containers or group packages, which are lifted off, a layer at a time.

12.2.2 Sweep-off depalletizer — A packaging machine which dismantles a loading unit, usually comprising rigid containers, which are gripped and pushed off, a layer at a time.

12.2.3 Robot depalletizer — A packaging machine which dismantles a loading unit, usually comprising group packages, which are lifted off one at a time.

12.3 Pallet securing machines

12.3.1 Pallet strapping machines

12.3.1.1 Vertical strapping machine — A packaging machine which applies a strap, usually metal or plastic, vertically around a loading unit.

12.3.1.2 Horizontal strapper — A packaging machine which applies a strap, usually metal or plastic, horizontally around a loading unit.

12.3.1.3 Pallet compression strapping machine — A packaging machine which compresses a palletized load before applying a series of straps to secure the load.

12.3.2 Pallet stretch wrappers

12.3.2.1 Rotating pallet stretchwrapper — A packaging machine which wraps a loading unit in thermoplastic film or net, applied in a spiral pattern from a reel while the loading unit is rotated.

12.3.2.2 Fixed pallet stretchwrapper — A packaging machine which wraps a loading unit in thermoplastic film or net, applied in a spiral pattern from a reel which is rotated around the stationary loading unit.

12.3.2.3 Two reel pallet stretchwrapper — A packaging machine which wraps a loading unit in thermoplastic film or net, applied in a spiral pattern from two reels which rotate around the stationary loading unit.

12.3.2.4 Stretch hood applicator — A packaging machine which wraps a loading unit in thermoplastic film, which is supplied as a reel of lay flat tubular film. A length of film is sealed at one end and then opened, stretched and placed over the loading unit.

12.3.3 Pallet shrinkwrapping machines

12.3.3.1 Shrink hood applicator — A packaging machine which wraps a loading unit in thermoplastic film, which is supplied as a reel of lay flat tubular film. A length of film is sealed at one end and then opened and placed over the loading unit.

12.3.3.2 Pallet shrink oven — A packaging machine which shrinks thermoplastic film around a pallet.

12.3.3.3 Pallet shrink tunnel — A packaging machine which shrinks thermoplastic film around a loading unit, as the units pass through the tunnel.

12.3.3.4 Pallet shrink frame — A packaging machine which shrinks thermoplastic film around a loading unit, by moving a heated frame over the surface of the film.

12.4 Ancillary equipment for pallets

12.4.1 Pallet dispenser — A packaging machine which dispenses empty pallets from a magazine or stack.

pallets from a magazine or stack.

12.4.2 Pallet stacker — A packaging machine which stacks loading units or empty pallets.

12.4.3 Pallet inverter — A packaging machine which inverts loading units, so that the pallet can be removed or changed.

12.4.4 Layer pad dispenser — A packaging machine or attachment which places layer pads onto layers of products as loading units are formed.

12.4.5 Layer pad removing machine — A packaging machine or attachment which removes layer pads from loading units as they are dismantled.

12.4.6 Top sheet dispenser — A packaging machine or attachment which places a sheet of thermoplastic material on top of a loading unit before it is stretchwrapped.

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Illnesses and Injuries Associated With the Use of Selected Dietary Supplements

This list of selected dietary supplements associated with serious safety problems is found in the section entitled "Illnesses and Injuries Associated With the Use of Selected Dietary Supplements" of an out-of-print 1993 FDA document "Unsubstantiated Claims and Documented Health Hazards in the Dietary Supplement Marketplace."

Products marketed as "dietary supplements" include a diverse range of products, from traditional nutrients, such as vitamins or minerals, to such substances as high-potency free amino acids, botanicals, enzymes, animal extracts, and bioflavanoids that often have no scientifically recognized role in nutrition.

There is currently no systematic evaluation of the safety of products marketed as dietary supplements. Dietary supplements routinely enter the marketplace without undergoing a safety review by FDA. Published studies on the safety of these products are extremely sparse. There is no systematic collection and review of adverse reaction reports for dietary supplements, as there is for drugs, and physicians rarely seek information about their patients' use of dietary supplements. Despite the lack of any system for gaining information about the risks of dietary supplements, an increased number of reports of adverse reactions to dietary supplement products has recently been recognized. Because of concern about these products, FDA has, in the last year, initiated an effort to collect and evaluate existing studies and case reports on safety problems associated with dietary supplements. As a result of that effort, FDA has begun to identify dietary supplements for which serious adverse reactions have been documented. A list of selected dietary supplements associated with serious safety problems follows. This list is not intended to include all hazardous ingredients in dietary supplements.

I. Herbals

Herbal and other botanical ingredients of dietary supplements include processed or unprocessed plant parts (bark, leaves, flowers, fruits, and stems), as well as extracts and essential oils. They are available in a variety of forms, including water infusions (teas), powders, tablets, capsules, and elixirs, and may be marketed as single substances or in combination with other materials, such as vitamins, minerals, amino acids, and non-nutrient ingredients. Although data on the availability, consumer use, and health effects

of herbals are very limited, some herbal ingredients have been associated with serious adverse health effects.

A. Chaparral (*Larrea tridentata*)

Chaparral, commonly called the creosote bush, is a desert shrub with a long history of use as a traditional medicine by Native Americans. Chaparral is marketed as a tea, as well as in tablet, capsule, and concentrated extract form, and has been promoted as a natural antioxidant "blood purifier," cancer cure, and acne treatment. At least six cases (five in the United States and one in Canada) of acute non-viral hepatitis (rapidly developing liver damage) have been associated with the consumption of chaparral as a dietary supplement. Additional cases have been reported and are under investigation. In the majority of the cases reported thus far, the injury to the liver resolves over time, after discontinuation of the product. In at least two patients, however, there is evidence that chaparral consumption caused irreversible liver damage. One patient suffered terminal liver failure requiring liver transplant.

Most of these cases are associated with the consumption of single ingredient chaparral capsules or tablets; however, a few of the more recent cases appear to be associated with consumption of multi-ingredient products (capsules, tablets or teas) that contain chaparral as one ingredient. Chemical analyses have identified no contaminants in the products associated with the cases of hepatitis. Products from at least four different distributors and from at least two different sources have been implicated thus far.

After FDA's health warning, many distributors of chaparral products voluntarily removed the products from the market in December of 1992. Some chaparral products remain on the market, however, and other distributors who removed their products from the market are seeking to clarify the status of these products.

B. Comfrey (*Symphytum officinale* (common comfrey), *S. asperum* (prickly comfrey), *S. X uplandicum* (Russian comfrey))

Preparations of comfrey, a fast-growing leafy plant, are widely sold in the United States as teas, tablets, capsules, tinctures, medicinal poultices, and lotions. Since 1985, at least seven cases of hepatic veno-occlusive disease--obstruction of blood flow from the liver with potential scarring (cirrhosis)--including one death, have been associated with the use of commercially available oral comfrey products.

Comfrey, like a number of other plants (e.g., *Senecio* species), contains pyrrolizidine alkaloids. The toxicity of pyrrolizidine alkaloids to humans is well-documented. Hepatic veno-occlusive disease following ingestion of pyrrolizidine alkaloid-containing products, has been documented repeatedly throughout the world. Hepatic veno-occlusive disease is usually acute and may result in fatal liver failure. In less severe cases, liver disease may progress to a subacute form. Even after apparent recovery, chronic liver disease, including cirrhosis, has been noted. Individuals who ingest small amounts of pyrrolizidine alkaloids for a prolonged period may also be at risk for development of

hepatic cirrhosis. The diagnosis of pyrrolizidine alkaloid-induced hepatic veno-occlusive disease is complex, and the condition is probably underdiagnosed.

The degree of injury caused by pyrrolizidine alkaloid-containing plants, like comfrey, is probably influenced by such factors as the age of the user, body mass, gender, and hepatic function, as well the total cumulative dose ingested and the type of exposure (i.e., whether exposure was to leaves or roots, infusions or capsules). Infants in general appear to be particularly susceptible to adverse effects of exposure to pyrrolizidine alkaloids; there are reports of infants developing hepatic veno-occlusive disease following acute exposure of less than one week. Transplacental pyrrolizidine poisoning has been suggested by the occurrence of hepatic disease in the newborn infant of a woman who consumed herbal tea during pregnancy.

Although liver damage is the major documented form of injury to humans from pyrrolizidine alkaloid-containing herbals, animal studies suggest that their toxicity is much broader. Animals exposed to pyrrolizidine alkaloids have developed a wide range of pulmonary, kidney and gastro-intestinal pathologies. Pyrrolizidine alkaloid-containing plants, including comfrey, have also been shown to cause cancer in laboratory animals.

Four countries (the United Kingdom, Australia, Canada, and Germany) have recently restricted the availability of products containing comfrey, and other countries permit use of comfrey only under a physician's prescription.

C. Yohimbe (*Pausinystalia yohimbe*)

Yohimbe is a tree bark containing a variety of pharmacologically active chemicals. It is marketed in a number of products for body building and "enchanced male performance." Serious adverse effects, including renal failure, seizures and death, have been reported to FDA with products containing yohimbe and are currently under investigation.

The major identified alkaloid in yohimbe is yohimbine, a chemical that causes vasodilation, thereby lowering blood pressure. Yohimbine is also a prescription drug in the United States. Side effects are well recognized and may include central nervous system stimulation that causes anxiety attacks. At high doses, yohimbine is a monoamine oxidase (MAO) inhibitor. MAO inhibitors can cause serious adverse effects when taken concomitantly with tyramine-containing foods (e.g., liver, cheeses, red wine) or with over-the-counter (OTC) products containing phenylpropanolamine, such as nasal decongestants and diet aids. Individuals taking yohimbe should be warned to rigorously avoid these foods and OTC products because of the increased likelihood of adverse effects.

Yohimbe should also be avoided by individuals with hypotension (low blood pressure), diabetes, and heart, liver or kidney disease. Symptoms of overdosage include weakness and nervous stimulation followed by paralysis, fatigue, stomach disorders, and ultimately death.

D. Lobelia (*Lobelia inflata*)

Lobelia, also known as Indian tobacco, contains pyridine-derived alkaloids, primarily lobeline. These alkaloids have pharmacological actions similar to, although less potent than, nicotine. There have been several reported cases of adverse reactions associated with consumption of dietary supplements containing lobelia.

Depending on the dose, lobeline can cause either autonomic nervous system stimulation or depression. At low doses, it produces bronchial dilation and increased respiratory rate. Higher doses result in respiratory depression, as well as sweating, rapid heart rate, hypotension, and even coma and death. As little as 50 milligrams of dried herb or a single milliliter of lobelia tincture has caused these reactions.

Because of its similarity to nicotine, lobelia may be dangerous to susceptible populations, including children, pregnant women, and individuals with cardiac disease. Lobelia is nevertheless found in dietary supplement products that are marketed for use by children and infants, pregnant women, and smokers.

E. Germander (*Teucrium* genus)

Germander is the common name for a group of plants that are contained in medicinal teas, elixirs and capsules or tablets, either singly or in combination with other herbs, and marketed for the treatment of obesity and to facilitate weight loss.

Since 1986, at least 27 cases of acute nonviral hepatitis (liver disease), including one death, have been associated with the use of commercially available germander products in France. These cases show a clear temporal relationship between ingestion of germander and onset of hepatitis, as well as the resolution of symptoms when the use of germander was stopped. In 12 cases, re-administration of germander was followed by prompt recurrence of hepatitis. Recovery occurred gradually in most cases, approximately two of six months after withdrawal of germander. Analyses of these cases does not indicate a strong relationship between the dosage or duration of ingestion and the occurrence of hepatitis.

Although the constituent in germander responsible for its hepatic toxicity has not been identified, germander contains several chemicals, including polyphenols, tannins, diterpenoids, and flavonoids.

On the basis of the 27 French hepatitis cases, the French Ministry of Health has forbidden the use of germander in drugs. Its use has been restricted in other countries.

F. Willow Bark (*Salix* species)

Willow bark has long been used for its analgesic (pain killing), antirheumatic, and antipyretic (fever-reducing) properties. Willow bark is widely promoted as an "aspirin-free" analgesic, including in dietary supplement products for children. Because it shares

the same chemical properties and the same adverse effects as aspirin, this claim is highly misleading. The "aspirin-free" claim is particularly dangerous on products marketed, without warning labels, for use by children and other aspirin-sensitive individuals.

The pharmacologically active component in willow bark is "salicin," a compound that is converted to salicylic acid by the body after ingestion. Both willow bark and aspirin are salicylates, a class of compounds that work by virtue of their salicylic acid content. Aspirin (acetylsalicylic acid) is also converted to salicylic acid after ingestion.

All salicylates share substantially the same side effects. The major adverse effects include irritation of the gastric mucosa (a particular hazard to individuals with ulcer disease), adverse effects when used during pregnancy (including stillbirth, bleeding, prolonged gestation and labor, and low-birth-weight infants), stroke, and adverse effects in children with fever and dehydration. Children with influenza or chickenpox should avoid salicylates because their use, even in small doses, is associated with development of Reye syndrome, which is characterized by severe, sometimes fatal, liver injury. Salicylate intoxication (headache, dizziness, ringing in ears, difficulty hearing, dimness of vision, confusion, lassitude, drowsiness, sweating, hyperventilation, nausea, vomiting, and central nervous system disturbances in severe cases) may occur as the result of over-medication, or kidney or liver insufficiency. Hypersensitivity, manifested by itching, broncho-spasm and localized swelling (which may be life-threatening), can occur with very small doses of salicylates, and may occur even in those without a prior history of sensitivity to salicylates. Approximately 5 percent of the population is hypersensitive to salicylates.

G. Jin Bu Huan

Jin Bu Huan is a Chinese herbal product whose label claims that it is good for "insomnia due to pain," ulcer, "stomachic ¬sic| neuralgia, pain in shrunken womb after childbirth, nervous insomnia, spasmodic cough, and etc." Jin Bu Huan has been recently reported to be responsible for the poisoning of at least three young children (ages 13 months to 2 2 years), who accidentally ingested this product. The children were hospitalized with rapid-onset, life-threatening bradycardia (very low heart rate), and central nervous system and respiratory depression. One child required intubation (assisted breathing). All three utlimately recovered following intensive medical care.

Although the product label identified the plant source for Jin Bu Huan as *Polygala chinensis*, this appears to be incorrect since preliminary analyses indicate the presence of tetrahydropalmatine (THP), a chemical not found in *Polygala*. THP is found, however, in high concentrations in plants of certain *Stephania* species. In animals, exposure to THP results in sedation, analgesia, and neuromuscular blockade (paralysis). The symptoms of the three children are consistent with these effects.

An additional case of THP toxicity, reported in the Netherlands, appears to be associated with the same product, and is being investigated.

H. Herbal products containing *Stephania* and *Magnolia* species

A Chinese herbal preparation containing *Stephania* and *Magnolia* species that was sold as a weight-loss treatment in Belgium has been implicated recently as a cause of severe kidney injury in at least 48 women. These cases were only discovered by diligent investigations by physicians treating two young women who presented with similar cases of rapidly progressing kidney disease that required renal dialysis. Once it was determined that both these women had used the herbal diet treatment, further investigation of kidney dialysis centers in Belgium found a total of 48 individuals with kidney injury who had used the herbal product.

At the time that a report of these adverse effects was published in February 1993, 18 of the 48 women had terminal kidney failure that will require either kidney transplantation or life-long renal dialysis.

I. Ma huang

Ma huang is one of several names for herbal products containing members of the genus *Ephedra*. There are many common names for these evergreen plants, including squaw tea and Mormon tea. Serious adverse effects, including hypertension (elevated blood pressure), palpitation (rapid heart rate), neurophathy (nerve damage), myopathy (muscle injury), psychosis, stroke, and memory loss, have been reported to FDA with products containing Ma huang as ingredients and are currently under investigation.

The *Ephedras* have been shown to contain various chemical stimulants, including the alkaloids ephedrine, pseudoephedrine and norpseudoephedrine, as well as various tannins and related chemicals. The concentrations of these alkaloids depends upon the particular species of *Ephedra* used. Ephedrine and pseudoephedrine are amphetamine-like chemicals used in OTC and prescription drugs. Many of these stimulants have known serious side effects.

Ma huang is sold in products for weight control, as well as in products that boost energy levels. These products often contain other stimulants, such as caffeine, which may have synergistic effects and increase the potential for adverse effects.

II. Amino Acids

Amino acids are the individual constituent parts of proteins. Consumption of foods containing intact proteins ordinarily provides sufficient amounts of the nine amino acids needed for growth and development in children and for maintenance of health of adults. The safety of amino acids in this form is generally not a concern. When marketed as dietary supplements, amino acids are sold as single compounds, in combinations of two or more amino acids, as components of protein powders, as chelated single compounds, or in chelated mixtures. Amino acids are promoted for a variety of uses, including body-building. Some are promoted for claimed pharmacologic effects.

The Federation of American Societies for Experimental Biology (FASEB) recently conducted an exhaustive search of available data on amino acids and concluded that there was insufficient information to establish a safe intake level for any amino acids in dietary supplements, and that their safety should not be assumed. FASEB warned that consuming amino acids in dietary supplement form posed potential risks for several subgroups of the general population, including women of childbearing age (especially if pregnant or nursing), infants, children, adolescents, the elderly, individuals with inherited disorders of amino acid metabolism, and individuals with certain diseases.

At least two of the amino acids consumed in dietary supplements have also been associated with serious injuries in healthy adults.

A. L-tryptophan

L-tryptophan is associated with the most serious recent outbreak of illness and death known to be due to consumption of dietary supplements. In 1989, public health officials realized that an epidemic of eosinophilia-myalgia syndrome (EMS) was associated with the ingestion of L-tryptophan in a dietary supplement. EMS is a systemic connective tissue disease characterized by severe muscle pain, an increase in white blood cells, and certain skin and neuromuscular manifestations.

More than 1,500 cases of L-tryptophan-related EMS have been reported to the national Centers for Disease Control and Prevention. At least 38 patients are known to have died. The true incidence of L-tryptophan-related EMS is thought to be much higher. Some of the individuals suffering from L-tryptophan-related EMS have recovered, while other individuals' illnesses have persisted or worsened over time.

Although initial epidemiologic studies suggested that the illnesses might be due to impurities in an L-tryptophan product from a single Japanese manufacturer, this hypothesis has not been verified, and additional evidence suggests that L-tryptophan itself may cause or contribute to development of EMS. Cases of EMS and related disorders have been found to be associated with ingestion of L-tryptophan from other batches or sources of L-tryptophan. These illnesses have also been associated with the use of L-5-hydroxytryptophan, a compound that is closely related to L-tryptophan, but is not produced using the manufacturing process that created the impurities in the particular Japanese product.

B. Phenylalanine

A number of illnesses, including those similar to the eosinophilia myalgia syndrome (EMS) associated with L-tryptophan consumption, have been reported to FDA in individuals using dietary supplements containing phenylalanine. There are also published reports of scleroderma/scleroderma-like illnesses, which have symptoms similar to EMS, occurring in children with poorly controlled blood phenylalanine levels, as well as in those with phenylketonuria (PKU), a genetic disorder characterized by the inability to metabolize phenylalanine.

III. Vitamins and Minerals

Vitamin and mineral dietary supplements have a long history of use at levels consistent with the Recommended Dietary Allowances (RDA's) or at low multiples of the RDA's, and are generally considered safe at these levels for the general population. Intakes above the RDA, however, vary widely in their potential for adverse effects. Certain vitamins and minerals that are safe when consumed at low levels are toxic at higher doses. The difference between a safe low dose and a toxic higher dose is quite large for some vitamins and minerals and quite small for others.

A. Vitamin A

Vitamin A is found in several forms in dietary supplements. Preformed vitamin A (vitamin A acetate and vitamin A palmitate) has well-recognized toxicity when consumed at levels of 25,000 International Units (IU) per day, or higher. (Beta-carotene does not have the potential for adverse effects that the other forms of vitamin A do, because high intakes of beta-carotene are converted to vitamin A in the body at much lower levels). The RDA for vitamin A is 1,000 retinol equivalents (RE) for men, which is equivalent to 3,300 IU of preformed vitamin A, and 80 percent of these amounts for women.

The adverse effects associated with consumption of vitamin A at 25,000+ IU include severe liver injury (including cirrhosis), bone and cartilage pathologies, elevated intracranial pressure, and birth defects in infants whose mothers consumed vitamin A during pregnancy. Groups especially vulnerable to vitamin A toxicity are children, pregnant women, and those with liver disease caused by a variety of factors, including alcohol, viral hepatitis, and severe protein-energy malnutrition.

There are some studies that suggest vitamin A toxicity has occurred at levels of ingestion below 25,000 IU. In addition, the severity of the injuries that occur at 25,000 IU suggests that substantial, but less severe and less readily recognized, injuries probably occur at somewhat lower intakes. Most experts recommend that vitamin A intake not exceed 10,000 IU for most adults or 8,000 IU for pregnant and nursing women.

B. Vitamin B_6

Neurologic toxicity, including ataxia (alteration in balance) and sensory neuropathy (changes in sensations due to nerve injury), is associated with intake of vitamin B_6 (pyridoxine) supplements at levels above 100 milligrams per day. As little as 50 milligrams per day has caused resumption of symptoms in an individual previously injured by higher intakes. The RDA for vitamin B_6 is 2 milligrams. Vitamin B_6 is marketed in capsules containing dosages in the 100-, 200-, and 500-milligrams range.

C. Niacin (nicotinic acid and nicotinamide)

Niacin taken in high doses is known to cause a wide range of adverse effects. The RDA for niacin is 20 milligrams. Niacin is marketed in dietary supplements at potencies of 250

mg, 400 mg, and 500 mg, in both immediate and slow-release formulations. Daily doses of 500 mg from slow-release formulations, and 750 mg of immediate-release niacin, have been associated with severe adverse reactions, including gastrointestinal distress (burning pain, nausea, vomiting, bloating, cramping, and diarrhea) and mild to severe liver damage. Less common, but more serious (in some cases life-threatening), reactions include liver injury, myopathy (muscle disease), maculopathy of the eyes (injury to the eyes resulting in decreased vision), coagulopathy (increased bleeding problems), cytopenia (decreases in cell types in the blood), hypotensive myocardial ischemia (heart injury caused by too low blood pressure), and metabolic acidosis (increases in the acidity of the blood and urine).

Niacin (nicotinic acid) is approved as a prescription drug to lower cholesterol. Many of the observed adverse reactions have occurred when patients have switched to OTC formulations of niacin, and particularly when they have switched from immediate-release formulations to dietary supplements containing slow-release niacin formulations without the knowledge of their physicians.

D. Selenium

Selenium is a mineral found in dietary supplement products. At high doses (approximately 800 to 1,000 micrograms per day), selenium can cause tissue damage, especially in tissues or organs that concentrate the element. The toxicity of selenium depends upon the chemical form of selenium in the ingested supplement and upon the selenium levels in the foods consumed. Human injuries have occurred following ingestion of high doses over a few weeks.

IV. Other Products Marked as Dietary Supplements

A. Germanium

Germanium is a nonessential element. Recently, germanium has been marketed in the form of inorganic germanium salts and novel organogermanium compounds, as a "dietary supplement." These products are promoted for their claimed immunomodulatory effects or as "health-promoting" elixirs. Germanium supplements, when used chronically, have caused nephrotoxicity (kidney injury) and death. Since 1982, there have been 20 reported cases of acute renal failure, including two deaths, attributed to oral intakes of germanium elixirs. In surviving patients, kidney function has improved after discontinuation of germanium, but none of the patients have recovered normal kidney function.

One particular organogermanium compound, an azaspiran organogermanium, has been studied for its potential use as an anticancer drug. Forty percent of the patients in this study experienced transient neurotoxicity (nerve damage), and two patients developed pulmonary toxicity. Because of these side effects, medically supervised administration of this drug with monitoring for toxicity has been recommended for those using germanium chronically.

FDA Website Search Results

Powered by Google

Searched for **medicinal teas** in **cfsan**. Results **1 - 8** of about **9**.Results are sorted by relevance. You can also sort by date (most recent result first).

"Cached" version:

- Highlights search keywords
- Displays text version of document

FDA/CFSAN/OPA: Agency Response Letter: GRAS Notice No. GRN **...**
... use of the remaining six herbs only in relation to herbal **teas** and **medicinal** uses. The PRC Pharmacopoeia provides multiple disease-related **medicinal** claims for **...**
www.cfsan.fda.gov/~rdb/opa-g013.html - 12-06-2000 - Cached

FDA/CFSAN: Illnesses and Injuries Associated With the Use of **...**
... is the common name for a group of plants that are contained in **medicinal teas**, elixirs and capsules or tablets, either singly or in combination with other herbs **...**
www.cfsan.fda.gov/~dms/ds-ill.html - 11-21-2000 - Cached

FDA/CFSAN - Guidance for Industry: Prior Notice of Imported **...**
... Guidance for Industry. Prior Notice of Imported Food: Harmonized Tariff Schedule Codes Flagged with Prior Notice Indicators. **...** Guidance to Industry. **...**
www.cfsan.fda.gov/~dms/htsguide.html - Large File: 101k - 12-17-2003 - Cached
[More results from www.cfsan.fda.gov/~dms/]

FDA/CFSAN Bad Bug Book Pyrrolizidine Alkaloids
... Most result from the use of **medicinal** preparations as home remedies. However, intoxications **...** remedies and consumption of herbal **teas** in large quantities can be **...**
www.cfsan.fda.gov/~mow/chap42.html - 01-22-2003 - Cached

[PDF] Economic Characterization of the Dietary Supplement Industry
... 5-3 Table 5-4 Herbal **Teas** Dollar Share and Sales Growth by Subcategory, January August 1997 Compared to January August 1996 **...**
www.cfsan.fda.gov/~acrobat/ds-econ.pdf - 10-15-1999 - Text Version

Federal Register - FR69 6787 Final Rule Declaring Dietary **...**
[Federal Register: February 11, 2004 (Volume 69, Number 28)] [Rules and **...**
www.cfsan.fda.gov/~lrd/fr040211.html - Large File: 101k - 02-11-2004 - Cached

FDA/CFSAN Small Business Labeling Exemption Requests
Skip Navigation **...** CFSAN/Office of Nutritional Products, Labeling and Dietary Supplements August 1, 2003. Small Business Labeling Exemption Requests. **...**
www.cfsan.fda.gov/~ear/sbellist.html - Large File: 101k - 11-14-2003 - Cached

2003 FDA Science Forum Abstracts
... consuming them in certain kinds of **teas** , tinctures, salves or other traditional **...** in cephalosporins is not acceptable in **medicinal** practice. The HPLC on C18 **...**
www.cfsan.fda.gov/~frf/forum03/abs03ct.html - Large File: 101k - 04-29-2003 - Cached

Illnesses and Injuries Associated With the Use of Selected Dietary Supplements

Protecting the Food Supply

October 2003

FDA Actions on New Bioterrorism Legislation

Fact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule - Registration of Food Facilities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Secretary of Health and Human Services to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply. To carry out the provisions of the Bioterrorism Act, FDA published, on October 10, 2003, an interim final regulation, *Registration Of Food Facilities*, which requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA. Under this interim final regulation, all affected facilities must register by ***December 12, 2003***. In the event of a potential or actual bioterrorism incident or an outbreak of food-borne illness, facility registration information will help FDA to determine the location and source of the event and permit the agency to notify quickly facilities that may be affected. **Facilities can register online via the Internet, by completing a paper form, or submitting to FDA a CD-ROM with relevant registration information. The online registration system will be available for use on *October 16, 2003*. For assistance with online registration: in the U.S call 1-800-216-7331 or 301-575-0156; from elsewhere call 301-575-0156; or send a fax to 301-210-0247. Requests for assistance also may be emailed to furls@fda.gov. Beginning October 16, 2003, the Online Registration Help Desk will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.**

This new regulation pertains *only* to facilities that manufacture/process, pack, or hold food, as defined in the regulation, for consumption in the U.S. Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals

- Animal feeds and pet food

Food contact substances and pesticides are not "food" for purposes of the interim final rule. Thus, a facility that manufactures/processes, packs, or holds a food contact substance or a pesticide is not required to register with FDA.

Who must register? The owner, operator, or agent in charge of a domestic or foreign facility that manufactures/processes, packs, or holds food for human or animal consumption in the U.S., or an individual authorized by one of them, must register that facility with FDA by **December 12, 2003**. A domestic facility must register whether or not food from the facility enters interstate commerce. A foreign facility must designate a **U.S. agent** (for example a facility's importer or broker), who must live or maintain a place of business in the U.S. and be physically present in the U.S., for purposes of registration.

What types of facilities do not have to register?

- ***Private residences of individuals***, even though food may be manufactured/processed, packed, or held there.
- ***Non-bottled water drinking water collection and distribution establishments and structures***, such as municipal water systems.
- ***Transport vehicles that hold food only in the usual course of their business as carriers***.
- ***Farms***, i.e., facilities in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling of produce are considered part of harvesting. The term "farm" also includes facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership, and facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. A farm-operated roadside stand that sells food directly to consumers as its primary function would be exempt from registration as a retail food establishment.
- ***Restaurants***, i.e., facilities that prepare and sell food directly to consumers for immediate consumption, including pet shelters, kennels, and veterinary facilities that provide food directly to animals. Facilities that provide food to interstate conveyances, such as commercial aircraft, or central kitchens that do not prepare and serve food directly to consumers are not restaurants for purposes of the rule.
- ***Retail food establishments***, such as groceries, delis, and roadside stands, that sell food directly to consumers as their *primary function*, meaning that annual sales directly to consumers are of greater dollar value than annual sales to other buyers. An establishment that manufactures/processes, packs, or holds food and whose primary function is to sell food directly to consumers, including food that the establishment manufactures/processes, from that establishment is a retail food establishment and is not required to register.

- ***Nonprofit food establishments***, which are charitable entities that meet the terms of § 501(c)(3) of the Internal Revenue Code and that prepare or serve food directly to the consumer or otherwise provide food or meals for consumption by humans or animals in the U.S. Central food banks, soup kitchens, and nonprofit food delivery services are examples of nonprofit food establishments.
- ***Fishing vessels*** that harvest and transport fish. Such vessels may engage in practices such as heading, eviscerating, or freezing fish solely to prepare the fish for holding on board the vessel and remain exempt.
- ***Facilities regulated exclusively and throughout the entire facility by the U.S. Department of Agriculture***, that is, facilities handling only meat, poultry or egg products.

Do all foreign facilities that manufacture/process, pack, or hold food for consumption in the U.S have to register? No. If a foreign facility that manufactures/ processes, packs, or holds food sends it to another *foreign* facility for further manufacturing/processing or packaging before the food is exported to the U.S., only the *second* foreign facility is required to register. **However**, if the second foreign facility performs only a *de minimis* activity, such as putting on a label, *both* facilities would be required to register. Also, any foreign facility that *packs or holds* food after the last foreign manufacturer/processor of the food must register.

How often must you register? Registration is required only once for each food facility. However, required registration information must be updated if it changes.

What does the registration number mean? It means that the owner of the facility has complied with this rule by registering with FDA. Assignment of the number does not convey FDA approval or endorsement of the facility or its products.

Is there a fee for registration? There is no fee for registration or for updates of any registration.

How can a facility register? Registrants must use Form 3537 to register or update a registration. Facilities may register online via the Internet at www.fda.gov/furls, which will operate 24 hours a day, seven days a week, beginning October 16, 2003. This web site is available from wherever the Internet is accessible, including libraries, copy centers, schools, and Internet cafes. In addition to the online help registrants can access at www.fda.gov/furls, there is also an Online Registration Help Desk:

- In the U.S call 1-800-216-7331 or 301-575-0156
- From elsewhere call 301-575-0156
- Fax questions to 301-210-0247
- Email questions to furls@fda.gov

Beginning October 16, 2003, these phone numbers will be staffed on business days from 7 AM until 11 PM U.S. Eastern Time.

If a facility does not have reasonable access to the Internet, a paper copy of the form may be obtained from FDA by calling 800-216-7331 or 301-575-0156 or by mailing a request to:

U.S. Food and Drug Administration
HFS-681
5600 Fishers Lane
Rockville MD 20857

When the form has been filled out completely and legibly, it should be mailed to the above address or faxed to (301) 210-0247. Also, as noted immediately below, registrations for multiple facilities may be submitted to FDA on a CD-ROM.

Is there a mechanism for registering multiple food facilities at one time? FDA will accept multiple registrations submitted in CD-ROM format ISO 9660 (CD-R or CD-RW) data format. These files must be submitted on a Portable Document Format (PDF) of Form 3537 and be accompanied by one signed copy of the certification statement that appears on the registration form. Each submission on the CD-ROM must use the same preferred mailing address in the appropriate block on Form 3537. There is no maximum number of registrations that may be submitted in this manner. However, each registration on a CD-ROM must have a unique file name up to 32 characters long, the first part of which may be used to identify the parent company. If the information does not conform to these specifications, FDA will not process the registration(s) and will return the CD-ROM for correction.

FDA will process CD-ROM submissions along with mailed and faxed submissions in the order received.

Why does FDA encourage electronic registration? FDA encourages this mode of registration as the least costly and most efficient means for the facility as well as FDA. With electronic registration, all required information must be entered before the system will accept the submission. At that point, registrants will receive immediate confirmation of registration and a registration number. Paper registration will be a more costly and less efficient process to supply both FDA with the necessary facility information and facilities with their registration numbers. Further, paper registration may have a higher number of errors or omissions on the form, requiring additional time to complete the registration process.

What information is required? Each registration must include the name, address, and phone number for the facility and its parent company (if applicable); the name, address, and phone number of the owner, operator, or agent in charge; all trade names the facility uses; applicable food product categories as identified in FDA's regulation, 21 CFR 170.3; a statement certifying that the information submitted is true and accurate and that the person submitting the registration, if not the owner, operator, or agent in charge, is authorized to submit the registration. A foreign facility must also provide the name, address, and phone number of its U.S. agent. The foreign facility must also provide the

emergency contact phone number for its U.S. agent unless the facility designates another person to serve as the emergency contact. A domestic facility must also provide an emergency contact phone number.

Is additional information requested? FDA is asking for, but not requiring, certain *optional* information on the registration form. The optional information will help us communicate more effectively with facilities that may be the target of an actual or potential terrorist threat or other food-related emergency. For example, some food products are not identified in the list of food categories at 21 CFR 170.3, such as certain dietary supplements, infant formula, and animal feed, but foods in these categories may be the focus of a food-related emergency. Therefore, FDA encourages, but does not require, submission of the information identified as optional on Form 3537.

Is registration information available to the public? No. Neither the list of registered facilities, any registration documents submitted under this regulation, nor any information derived from the list or the documents that would reveal the identity or location of a specific registered person is subject to disclosure under the Freedom of Information Act (FOIA).

What if the submitted registration information changes? When a required element of a facility's registration information changes, e.g., change of operator, agent in charge, or U.S. agent, the owner, operator, or agent in charge, or an individual authorized by one of them, must submit an update to the facility's registration within 60 days of the change through the Internet at www.fda.gov/furls or through the paper update process.

What if a facility goes out of business? When a facility goes out of business, its registration must be canceled using Form 3537a, either through the Internet, at www.fda.gov/furls, or through the paper process.

What if a new owner acquires an already-registered facility? The former owner must cancel the facility's registration within 60 days of the change (using Form 3537a), and the new owner must re-register the facility using Form 3537. Both cancellation and re-registration may be completed through the Internet or through the paper process.

What happens if a facility does not register? Failure of a domestic or foreign facility to register, update required elements, or cancel its registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. The Federal government can bring a civil action to ask a Federal court to enjoin persons who commit a prohibited act, or it can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act. If a foreign facility is required to register but fails to do so, food from that foreign facility that is offered for import into the U.S. is subject to being held within the port of entry for the article unless otherwise directed by FDA or the Bureau of Customs and Border Protection (CBP). FDA plans to issue enforcement guidance regarding the agency's policies regarding refusals of imported food under section 801(m)(1) or holds of imported food under section 801(l).

This guidance document will be available to the public, and FDA will publish a notice of its availability in the Federal Register.

Will additional comments be accepted on this interim final regulation? FDA is providing a 75-day comment period on specific issues related to this interim final rule. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period for an additional 30 days beginning in March 2004. Regularly updated information on this interim final rule and how to comment on it can be accessed electronically at http://www.fda.gov/oc/bioterrorism/bioact.html.

How will FDA enforce this interim final rule during the comment period? FDA will actively consider the exercise of its discretion in the enforcement of the Registration interim final rule while at the same time ensuring public health protection, both during initial implementation of the rule and thereafter. The Registration interim final rule takes effect on December 12, 2003 and covered entities are responsible for complying with the requirements in the rule at that time. FDA recognizes that a number of affected parties still may need assistance in understanding the rule's requirements and how to comply even after the extensive outreach and educational activities that FDA will be conducting before December 12th. Accordingly, for this and other reasons, FDA intends to put into place, during the initial months following the effective date, a policy that emphasizes assisting covered entities in understanding the requirements and how to comply. FDA will shortly publish a notice of availability for a Compliance Policy Guide that will outline how FDA generally intends to exercise its enforcement discretion. This guidance, however, will not affect FDA's ability to take actions that may be necessary, including conducting inspections for food safety and security concerns or taking any other action under the Federal Food, Drug, and Cosmetic Act. This policy will also not affect the ability of the Bureau of Customs and Border Protection to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

For further information: For more details and information on the specific requirements of this interim final rule, please refer to the interim final rule itself. The interim final rule is available at http://www.cfsan.fda.gov/~furls/ffregfr.html.