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)

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

A Food Labeling Guide

Table of Contents

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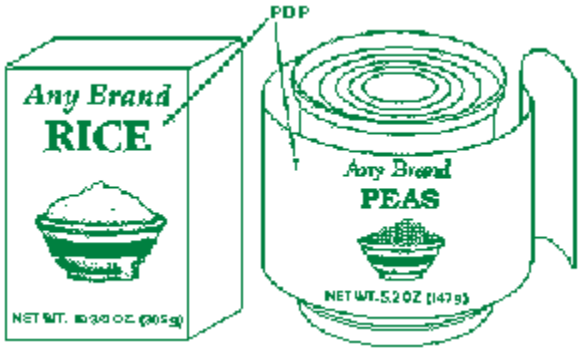
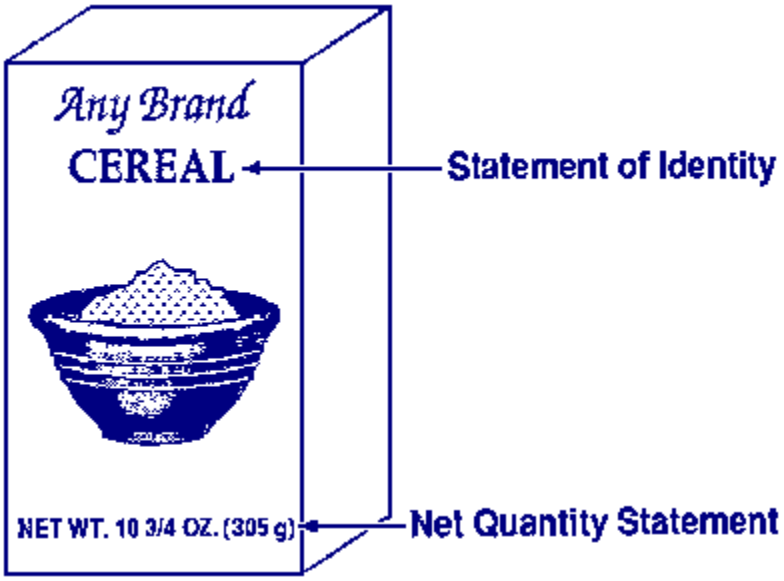
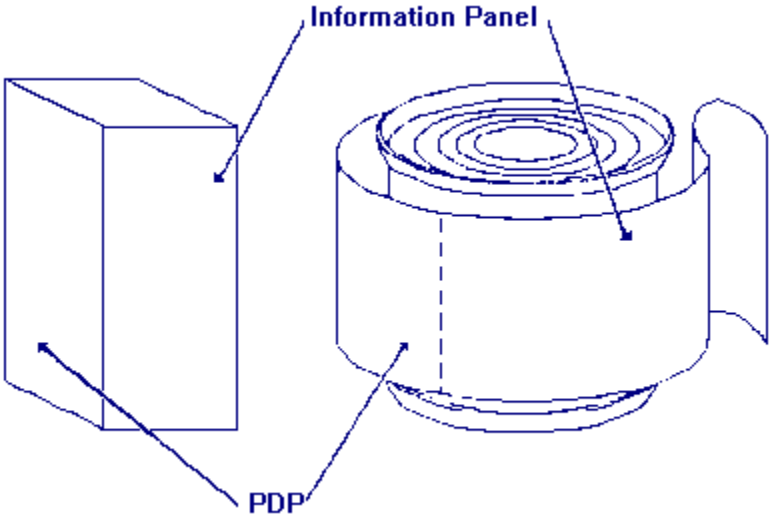
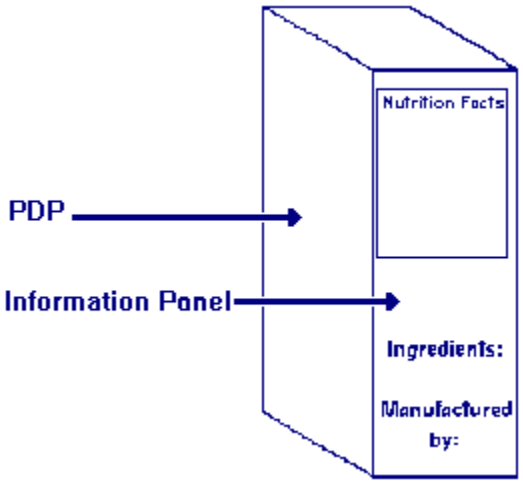
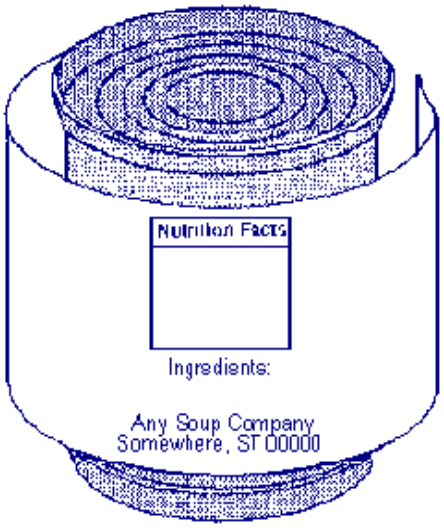
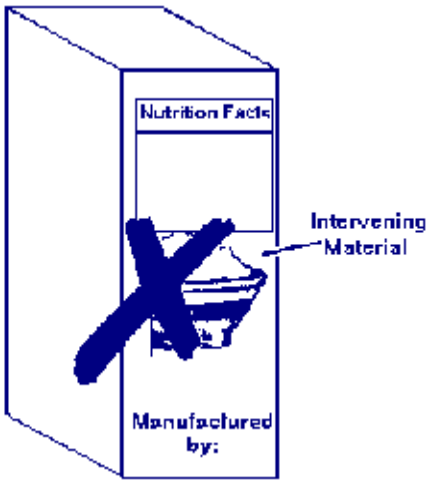
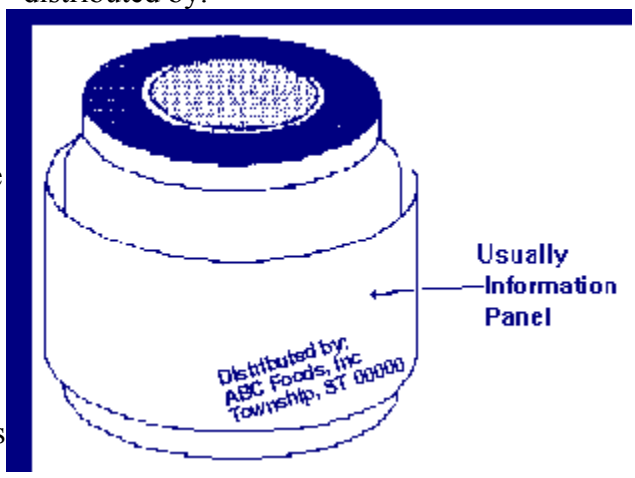
Chapter I--General Food Labeling Requirements

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

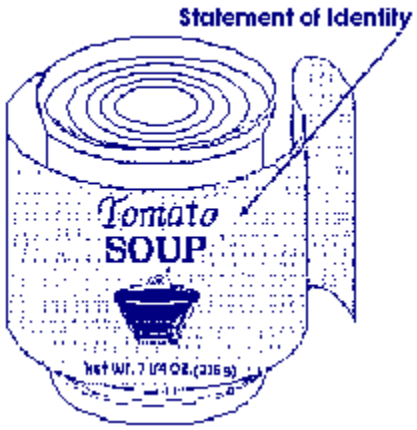


Questions	Answers
3. What label statements must appear on the principal display panel?	Place the statement of identity, or name of the food, and the net quantity statement, or amount of product, on the PDP and on the alternate PDP. The required type size and prominence are discussed in Chapters 2 and 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)

Questions	Answers
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)

Questions	Answers
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

A Food Labeling Guide
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)

Questions	Answers
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)

Questions	Answers
9. What **type size** and **degree of prominence** is required for the word "imitation" in the product name?	Use the same type size and prominence for the word "imitation" as is 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)

Questions	Answers
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:

Questions	Answers
	(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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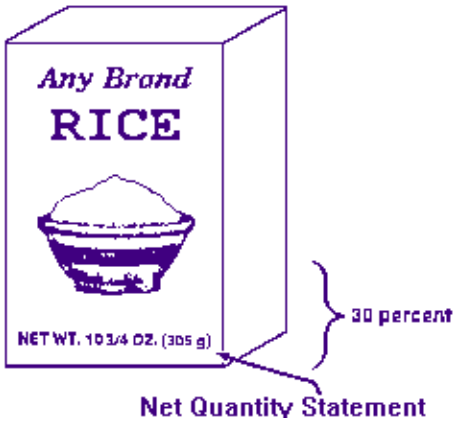
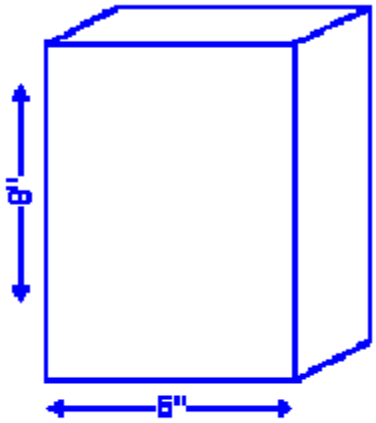
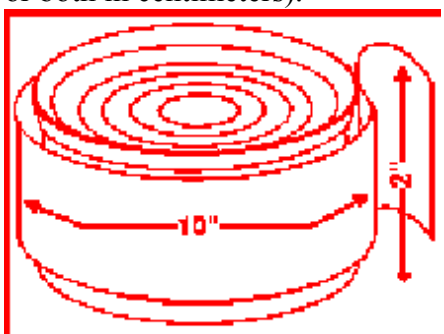
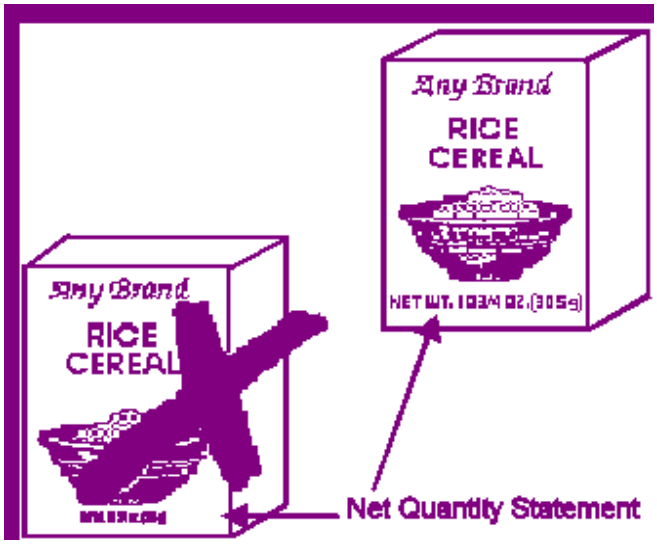
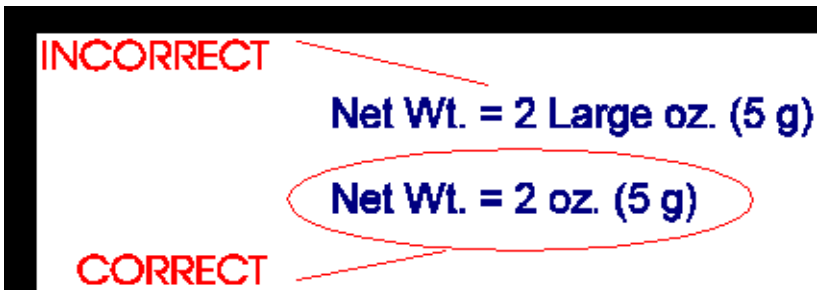
Chapter III--Net Quantity of Contents Statements

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

Questions	Answers
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

Questions	Answers
	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)

Questions	Answers
8. Is water or other packing medium included in determining the net quantity of contents in a food container?	The water or other liquid added to food in a container is usually included in 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)

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)

Questions	Answers
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)

Questions	Answers
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: **Certified colors: List by specific or abbreviated name such as "FD&C Red No. 40" or "Red 40."** **Non-certified colors: 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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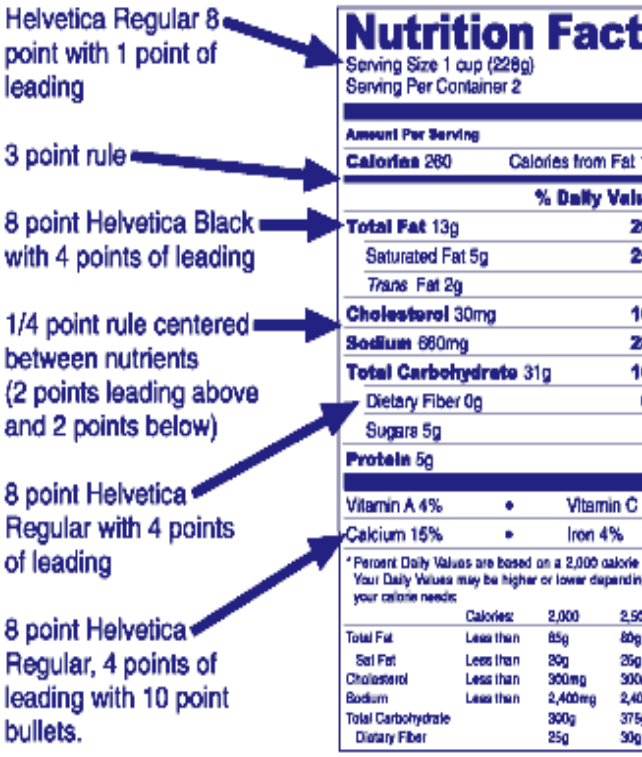
Chapter V--Nutrition Labeling

Questions	Ans
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 packag help assure readibility and conspicuousness. Not all of these type specifications are required. T this booklet, (1) Any legible type style may be used, not just Helvetica, (2) The heading "Nutri point, but does not need to be 13-point, and (3) There is no specific thickness required for the t 21 CFR 101.9(a) and 101.9(a)(1) Below are listed categories providing exemptions or special provisions for nutrition labeling. A nutrition information is provided: Summary of Exemption *Manufactured by small businesses *Food served in restaurants, etc. or delivered to homes ready for immediate consumption *Delicatessen-type food, bakery products and confections that are sold directly to consumers from the location where prepared *Foods that provide no significant nutrition such as instant coffee (plain, unsweetened) and most spices Infant formula, and infant and junior foods to 4 years (modified label provisions for these categories) Dietary supplements (must comply with 21 CFR 101.36) Medical foods Bulk foods shipped for further processing or packaging before retail sale *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) 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. Certain egg cartons (nutrition information inside lid or on insert in carton)

Questions	Ans
	Packages labeled "This unit not labeled for retail sale" within multiunit package, and outer wrapper bears all required label statements Self-service bulk foods--nutrition labeling by placard, or on original container displayed clearly in view Donated food that is given free (not sold) to the consumer. Game meats may provide required nutrition information or labeling in accordance with 21 CFR 101.9(a)(2).
2. Are nutrition designations permitted on food package labels?	FDA considers information that is required or permitted in the "Nutrition Facts" panel on the f 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 ad packer, or distributor) on the principal display panel (PDP). These three label statements also r panel adjacent and to the right of the principal display panel, or, if there is insufficient space or the right). On packages with insufficient area on the principal display panel and information pa 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 "N requirements are specified in 21 CFR 101.9(d)	

Questions	Ans



A. Overall

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

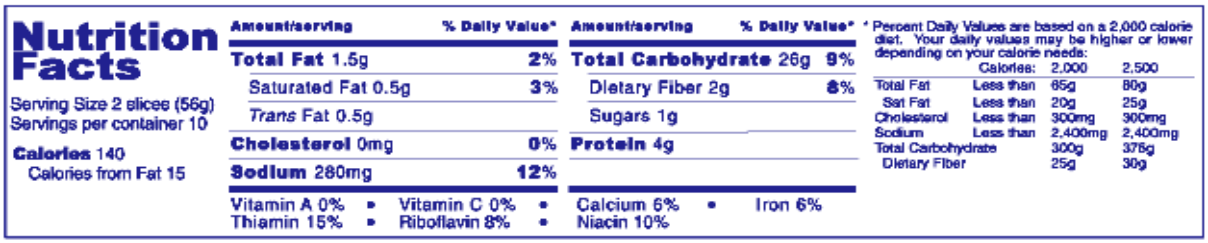
B. Typeface and Size

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

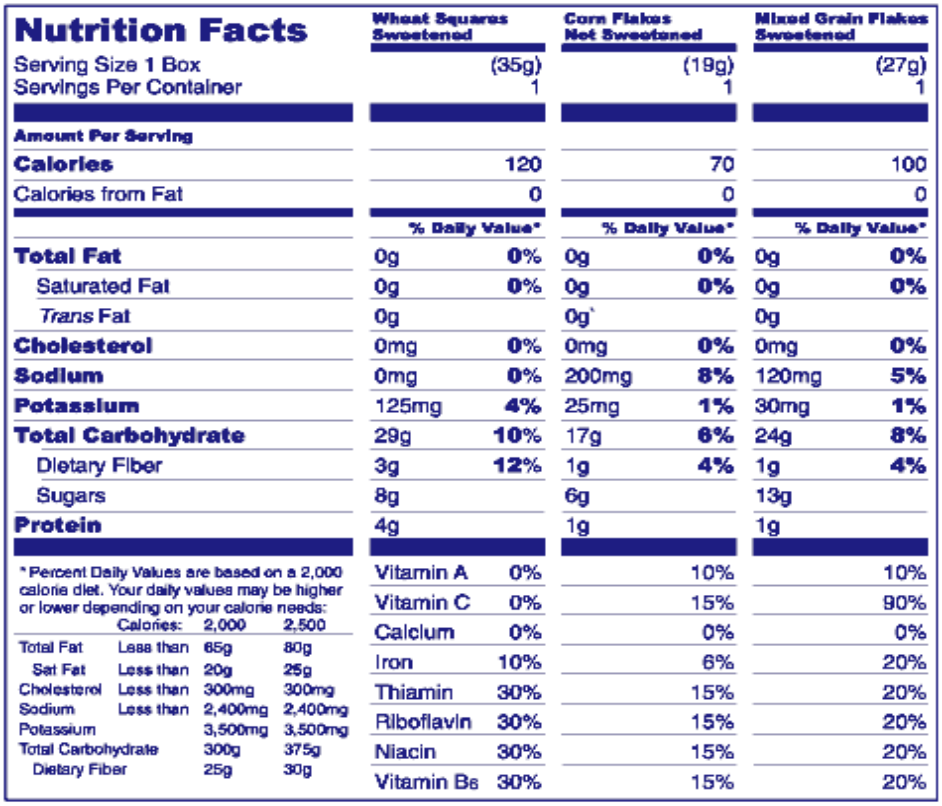
C. Rules

1. A 7 point rule separates large groupings as shown in the example. A 3 point rule separates calorie inform
2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example. Descenders do n
   the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and

D. Box

Questions	Ans
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 b "Nutrition Facts" label does not fit. In this format, the bottom part of the "Nutrition Facts" label (followin information) is placed immediately to the right and separated with a line. If additional vitamins and mine and the space under iron is inadequate, they may also be listed to the right with a line that sets them apart Also, if the package has insufficient continuous vertical space (ie., about 3 inches) to accomodate the abo 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* **Total Fat** 1.5g — 2% Saturated Fat 0.5g — 3% *Trans* Fat 0.5g **Cholesterol** 0mg — 0% **Sodium** 280mg — 12% Amount/serving — % Daily Value* **Total Carbohydrate** 26g — 9% Dietary Fiber 2g — 8% Sugars 1g **Protein** 4g 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 the same type of food, such as round ice cream containers, the manufacturer may choose to include separ Facts" panel.	

Questions	Ans



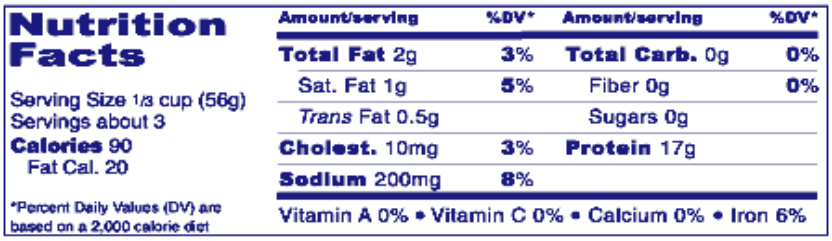
Nutrition Facts	Wheat Squares Sweetened		Corn Flakes Not Sweetened		Mixed Grain Flakes Sweetened	
Serving Size 1 Box	(35g)		(19g)		(27g)	
Servings Per Container	1		1		1	
Amount Per Serving						
Calories	120		70		100	
Calories from Fat	0		0		0	
		% Daily Value*		% Daily Value*		% Daily Value*
Total Fat	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 "Nu footnotes to the "Nutrition Facts" label if another asterisk is placed at the bottom of the label w the tabular display label format.



Nutrition Facts	Amount/serving	%DV*	Amount/serving	%DV*
Serving Size 1/3 cup (56g)	**Total Fat** 2g	3%	**Total Carb.** 0g	0%
Servings about 3	Sat. Fat 1g	5%	Fiber 0g	0%
Calories 90	*Trans* Fat 0.5g		Sugars 0g	
Fat Cal. 20	**Cholest.** 10mg	3%	**Protein** 17g	
	Sodium 200mg	8%		

*Percent Daily Values (DV) are based on a 2,000 calorie diet

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

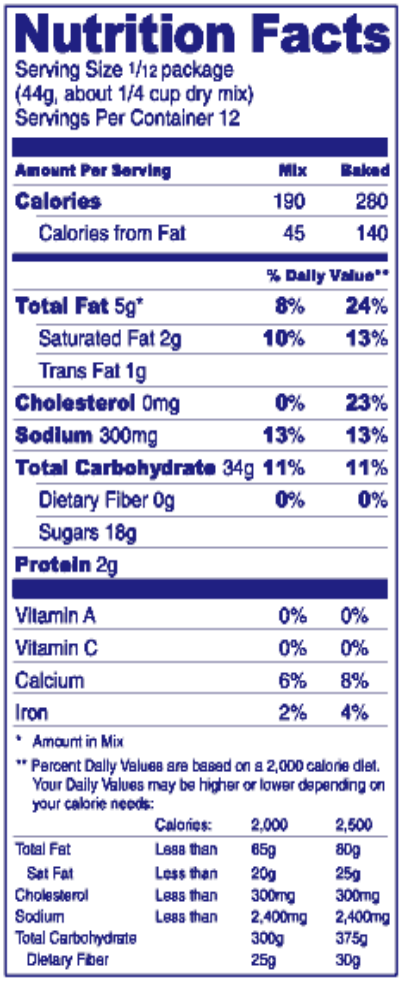
21 CFR 101.9(j)(13)(ii)(A)

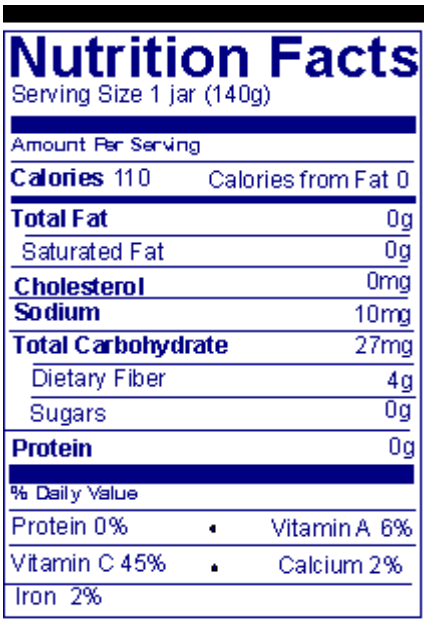
9. Is there **another exemption** if the tabular display label does not fit on **small and intermediate-**	A linear (string) format may be used on food packages with 40 sq. in. or less total surface area information placed in columns on any label panel.

Questions	Ans
sized packages?	**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 follov 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 21 CFR 101.9(j)(13)(ii)(B)

Questions	Ans
11. What is the "telephone number exemption" for small food packages?	 Small packages (less than 12 sq. in. total surface area available to b information. This exemption (using a telephone number or address 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 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 portion of the serving size declaration. However, if it is voluntarily included, it must be consist size for single-serving containers must be a description of the container such as: "Serving Size for foods in plastic containers, or "Serving Size: 1 can" as appropriate. Only those few foods th the metric equivalent as part of the serving size declaration, e.g., "Serving size: 1 can drained (21 CFR 101.9(b)(5)(iv), 101.9(b)(7) & 101.9(d)(3)(ii)

Questions	Ans
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 cons add a second column of nutrition information showing calories, calories from fat and the % Da amounts (i.e., g/mg) need only be given for the packaged food. However, as shown in this exa nutrients in the added food. Alternatively, the quantitative amounts of the prepared food may b food (e.g., "Sodium 200 mg, 265 mg"). 21 CFR 101.9(e)

Questions	Ans
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**?	 When the nutrient values in the column for the product prepare packaged (e.g., the only ingredients added during preparation a amount made as part of the serving size declaration. For examp prepared)." 21 CFR 101.9(b)(7)(v), 101.9(e), 101.9(e)(5)
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 % D children less than 2 years of age must not present information on calories from fat and calories monounsaturated fat and cholesterol. In both cases, % Daily Value is declared only for protein Fruit dessert for children less than 2 years old — [redacted] Fruit dessert for children ages 2 years to 4 years — [redacted]

Questions	Ans
	 21 CFR 101.9(j)(5)(i)  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 se ("not a significant source of _____") immediately below the listing of vitamins A and C,

Nutrient	Level per serving	Label s
Calories from fat 21 CFR 101.9(c)(1)(ii)	Less than 0.5 g fat	"Not a
Saturated fat 21 CFR 101.9(c)(2)(i)	Less than 0.5g of total fat	"Not a
Cholesterol 21 CFR 101.9(c)(3)	Less than 2 mg	"Not a
Dietary fiber 21 CFR 101.9(c)(6)(i)	Less than 1g	"Not a
Sugars 21 CFR 101.9(c)(6)(ii)	Less than 1g	"Not a
Vitamins A and C, calcium, and iron 21 CFR 101.9(c)(8)(iii)	Less than 2% of RDI	"Not a

Questions	Ans
	
18. Is there a "Nutrition Facts" format for a food in which most nutrients are present in insignificant amounts?	 A simplified "Nutrition Facts" label may be used if at least sev fat, cholesterol, sodium, total carbohydrate, dietary fiber, suga intended for children less than 2 years). The five core nutrients regardless of amounts present in the food. In addition, any of t to the food must be "declared on the simplified "Nutrition Fact 21 CFR 101.9(f) - List of nutrients, 101.9(f)(1) - "Insignificant

Questions	Ans
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 nutrien "Nutrition Facts" label, and when claims are made on the label. In this example, the manufactu and therefore must add the statement "Not a significant source of _____" with the blank f 21 CFR 101.9(f)(4)
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 m soluble and insoluble fiber, sugar alcohol, other carbohydrates, vitamins and minerals for whic 21 CFR 101.9(c)
21. Is there a **restriction** against **certain nutrients** on the "Nutrition Facts" label?	Only those nutrients listed in FDA's nutrition regulations, as mandatory or voluntary componer 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 nutrients are added to the food, if the label makes a nutrition claim (such as a nutrient content c 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 cal added directly to the packaged food (e.g., enriched bread), but not when the enriched product i NOTE: It is necessary to declare the other vitamins and minerals in the ingredient list. Howeve nutrients (i.e., thiamin, riboflavin, niacin, and folic acid) would have to be declared on the "Nu 21 CFR 101.9(c)(8)(ii)(A)-(B), & 101.9(c)(8)(iv)

Questions	Ans
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 either fluid ounces, cups, or fractions of a cup with the metric equivalent in milliliters (mL). Th 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 multise 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 followi (454g) pizza: ***1st step:*** From the reference amounts table (21 CFR 101.12(b)), you determine that the ***2nd step:*** Calculate the fraction of the pizza that is closest to the reference amount of 1 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 t **Example: "Serving Size 1/3 pie (151g)"** Therefore, the serving size is "1/3 pizza (151g)" for this example, whereas the reference amoun Note: Sections 101.9(b)(2)(i) (discrete units), 101.9.(b)(2)(ii) (large discrete units), and 101.9(21 CFR 101.12(b)

Questions	Ans
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 s ***1st step:*** From the reference amounts table (21 CFR 101.12(b)), determine that the refe ***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 an ***4th step:*** The serving size is the fraction of a tablespoon or cup of biscuit mix determin size. Use the form "Serving Size __ cup (__ g)," the blanks filled in with correct values for t Reference amounts: 21 CFR 101.12(b)&(c)
27. Is it necessary to **reformulate the size of a product** such as cookies so that the **serving size** weighs exactly the reference amount (i.e., 30g)?	It is not necessary to adjust the size of your cookies to fit the reference amount. For example, i cookies nearest the reference amount and label with the exact weight of that number of cookie 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 serving size in whole numbers (such as 4 fl oz, 5 fl oz, 6 fl oz, etc). For tablespoons, the follow For teaspoons, the fracations of a teaspoon shall be expressed as 1/8, 1/4, 1/2, 3/4, 1, or 2 teasp 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 further division by 2 or 3. 21 CFR 101.9(b)(2)(ii)

Questions	Ans
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 amount) may be declared as a serving if the whole slice can reasonably be eaten at a single-eat may be declared as either one or two slices. For slices weighing less than 50% of the reference 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 neares *Examples:* "2 servings," "2-1/2 servings," "3 servings," "3-1/2 servings," "4 servings," "4-1/2 s For packages containing five or more servings, round the number of servings to the nearest wh *Examples:* "5 servings," "6 servings," "7 servings." Rounding should be indicated by the term " 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 co contain 200% or more of the reference amount, it is the manufacturer's option to label the prod 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 les reference amount to be labeled as 2 servings. For foods with reference amounts of 100g or 100 200% 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"**

Questions	Ans
	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 **Total fat = Weight of all individual fatty acids + weight of one unit of glycerol for** 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 ab **Examples: 5 g, 6 g, 7 g, etc.** 21 CFR 101.9(c)(2)
37. How is **"total carbohydrate"** calculated?	"Total carbohydrate" is calculated by subtracting the weight of crude protein, total fat, moistur 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 monosac 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 nu variable. The variables that affect nutrient levels should be determined, and a sampling plan sh

Questions	Ans
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 and validate the resulting calculations by comparing them with values for the same foods obtai labeling values on their products. Although FDA specifies the laboratory methods that will be sources for the labeled values.
41. What values are used for calculating Daily Values for the nutrition label?	See "Reference Values for Nutritional Labeling".

A Food Labeling Guide

Chapter VI--Claims

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)

Questions	Answers
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)

Questions	Answers
11. Could a statement of identity ever be considered **"intervening material"**?	Yes, if the claim and the statement of identity were separate pieces of information on the label. If the statement of identity and the 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)

Questions	Answers
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 statements required on meal-type products?	A meal (see 21 CFR 101.13(l) for definition of a "meal") must be 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)

Questions	Answers
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)
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)

Questions	Answers
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

Questions	Answers
	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).

Questions	Answers
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).

Questions	Answers
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)

Questions	Answers
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"

Individual Food	Seafood/Game Meat	Meals/Main Dish
	TOTAL FAT	
low fat	< 5 g fat/RA & 100g	low 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

A Food Labeling Guide--Appendix A

Definitions of Nutrient Content Claims

Nutrient	Free	Low	
	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"	Synonym ("Fewer" "Modifie identity Definitio same as f basis

Nutrient	Free	Low	
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 per 100 g	At least 2 amount th Reference Uses term

Nutrient	Free	Low	
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 2 amount th Reference
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	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	At least 2 amount th Reference

Nutrient	Free	Low	
	less than 0.5 g trans fatty acids per labeled serving) No ingredient that is understood to contain saturated fat except as noted below(*)	and less than 10% of calories from saturated fat	Fat"
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	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	At least 2 amount th Reference Cholester

Nutrient	Free	Low	
	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)	(5% of market) Meals and main dishes: 20 mg or less per 100 g	
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 main dishes: 140 mg or less per	At least 2 amount th Reference

Nutrient	Free	Low	
	No ingredient that is sodium chloride or generally understood to contain sodium except as noted below(*)	100g	

Nutrient	Free	Low	
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 ingredient that is a sugar or generally understood to contain sugars except as noted below(*)	Not Defined. No basis for recommended intake	At least 2 amount th May not suppleme

Nutrient	Free	Low	
	Disclose calorie profile (e.g., "Low Calorie")		

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

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.

A Food Labeling Guide--Appendix C

Health Claims

Approved Claims	Food Requirements	Claim Requirements	
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:	Regular calcium Asian w may rec in life.

Approved Claims	Food Requirements	Claim Requirements	
		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.	
Sodium and Hypertension-- 21 CFR 101.74	- Low sodium	*Required terms:* - "Sodium", "High blood pressure" Includes physician statement (Individuals with	Diets lo blood p factors.

Approved Claims	Food Requirements	Claim Requirements	
		high blood pressure should consult their physicians) if claim defines high or normal blood pressure	
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.	Develo factors. risk of s

Approved Claims	Food Requirements	Claim Requirements	
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--cholesterol.	While r low in s the risk

Approved Claims	Food Requirements	Claim Requirements	
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 product risk of associat
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,	*Required terms:* - "Fiber", "Dietary fiber", "Some types of dietary fiber", "Some dietary fibers", or "Some fibers" - "Saturated fat" and "Cholesterol"	Diets lo rich in contain soluble disease

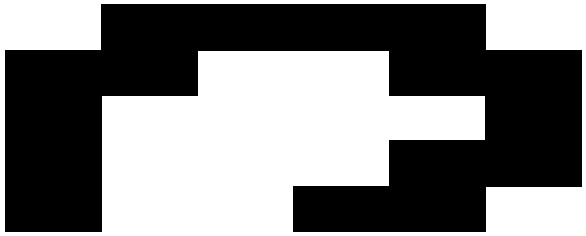
Approved Claims	Food Requirements	Claim Requirements	
	- Low cholesterol, - Low fat, - At least 0.6 grams of soluble fiber per RA (without fortification), and, - Soluble fiber content provided on label	- "Heart disease" or "Coronary heart disease" Includes physician statement ("Individuals with elevated blood total--or LDL--cholesterol should consult their physicians") if claim defines high or normal blood total--and LDL--cholesterol.	
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:	*Required terms:* - "Fiber", "Dietary fiber", or "Total dietary fiber"; - "Total fat" or "Fat", - "Some types of cancer" or "Some cancers"	Low fa that are Vitamin some ty many fa C, and

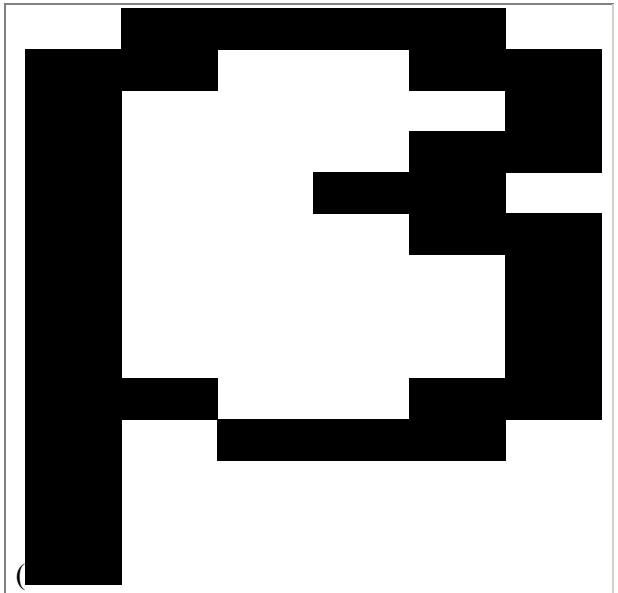
Approved Claims	Food Requirements	Claim Requirements	
	one of the following: Vitamin A, Vitamin C, or Dietary fiber	Characterizes fruits and vegetables as "Foods that are low in fat and may contain Vitamin A, Vitamin C, and dietary fiber." Characterizes specific food as a "Good source" of one or more 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.	
Folate and Neural Tube Defects-- 21 CFR 101.79	"Good source" of folate (at least 40 mg folate per serving) - Dietary supplements, or foods in conventional food form that are naturally good sources of	*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	Healthf a woma spinal c

Approved Claims	Food Requirements	Claim Requirements	
	folate (i.e., only non-fortified food in conventional food 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.	vitamin", "folic acid, a B vitamin," "folacin, a 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	
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	**Full cla** consum starches alcohol decay. **Shorte** Does no

Approved Claims	Food Requirements	Claim Requirements	
		surface area available for labeling may use a shortened claim.	
Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease - 21 CFR 101.81	-Low saturated fat -Low cholesterol -Low fat -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	*Required terms:* - "Heart disease" or "coronary heart disease." - "Soluble fiber" 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."	Soluble *soluble* *food pr* fat and disease supplie intake f *of solub* have th

Approved Claims	Food Requirements	Claim Requirements	
	nutrition label. **Eligible Source of Soluble Fiber** Beta 	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))	

Approved Claims	Food Requirements	Claim Requirements
	 ( ) glucan soluble fiber from oat bran, rolled oats (or oatmeal), and whole oat flour. Oat bran must provide at least 5.5% 	

Approved Claims	Food Requirements	Claim Requirements	
Soy Protein and Risk of Coronary Heart Disease 21 CFR 101.82	- At least 6.25 g soy protein per RA - Low saturated fat, - 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)	*Required terms:* - "Heart disease" or "coronary heart disease" - "Soy protein" - "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	(1) 25 g diet low reduce [*name o* (2) Diet include reduce [*name o*
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	*Required terms:* - " May" or " might" reduce the risk of CHD - " Heart disease" or " coronary heart disease" - " Plant sterol esters" or " plant stanol esters" ;	(1) Foo serving a day w least 1. fat and

Approved Claims	Food Requirements	Claim Requirements	
	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)	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 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.	disease grams o (2) Diet include daily to esters i disease grams o

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:

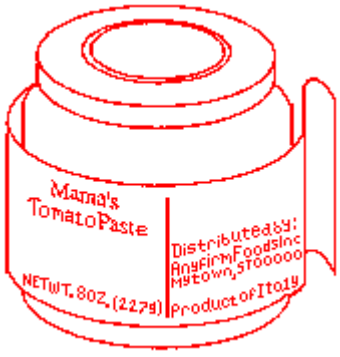
Disqualifying Nutrients	Foods	Main Dishes	Meal Products
Fat	13 g	19.5 g	26 g
Saturated Fat	4 g	6 g	8 g
Cholesterol	60 mg	90 mg	120 mg
Sodium	480 mg	720 mg	960 mg

Abbreviations: RA = reference amount, IU = International Units

A Food Labeling Guide

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.	

Questions	Answers
	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 Diarios 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)

Questions	Answers
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.

A Food Labeling Guide
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

Key Word Index

This is a listing that will be helpful to you in locating your food labeling areas of concern. The designated chapters contain questions addressing the listed areas.

A Food Labeling Guide

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

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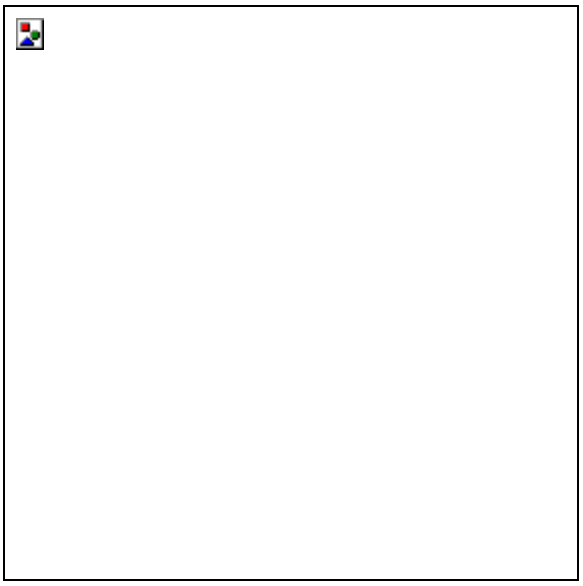

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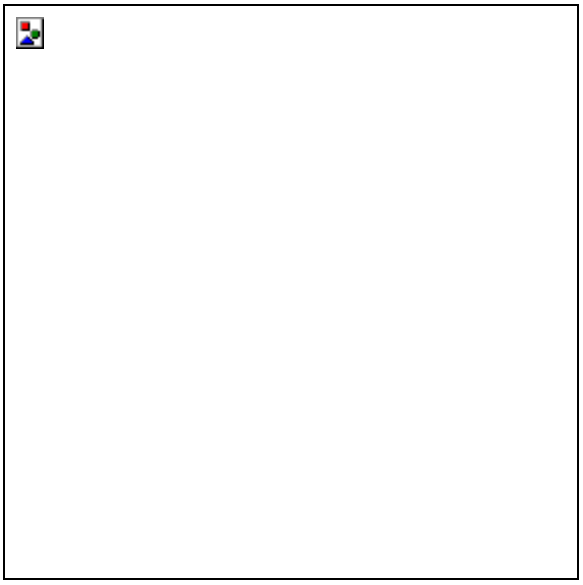
Center for Food Safety and Applied Nutrition



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