CFSAN/Office of Nutrition, Labeling, and Dietary Supplements
April 2008

Guidance for Industry

A Food Labeling Guide

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
April 2008

Contains Nonbinding Recommendations

Guidance for Industry[(1)]

A Food Labeling Guide

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Table of Contents

I. Introduction

In a guide 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 area of interest. The Table of Contents will help you locate your food labeling area of interest.

Under FDA's laws and regulations, FDA does not pre-approve labels for food products. Questions concerning the labeling of food products may be directed to the Food Labeling and Standards Staff (HFS-820), Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835, Telephone: (301) 436-2371.

II. Background

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 guidance 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 (NLEA), 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 guidance, regulations are frequently changed. It is the responsibility for the food industry to remain current with the legal requirements for food labeling. All new regulations are published in the Federal Register (FR) prior to their effective date and compiled annually in Title 21 of the Code of Federal Regulations (CFR).

(1) This guidance has been prepared by the Office of Nutritional Products, Labeling, and Dietary Supplements in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

The document above supercedes the previous version issued in September 1994.

U.S. Food and Drug Administration
Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

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Chapter III. General Food Labeling Requirements

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1. Where should label statements be placed on containers and packages?

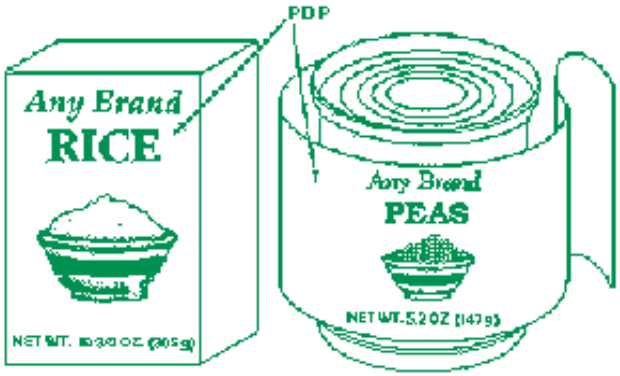
Answer: There are two ways to label packages and containers:

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 PDP and other labeling on the information panel (the label panel immediately to the right of the PDP, as seen

by the consumer facing the product).

21 CFR 101.2, 21 CFR 101.3, 21 CFR 101.4, 21 CFR 101.9, and 21 CFR 101.105,

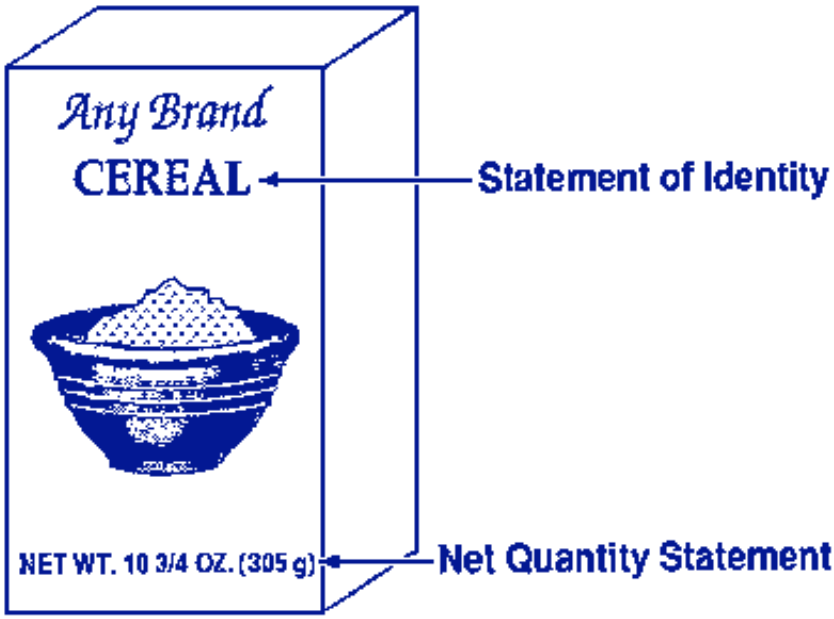
2. What are the PDP and the alternate PDP?



Answer: The 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 PDPs.

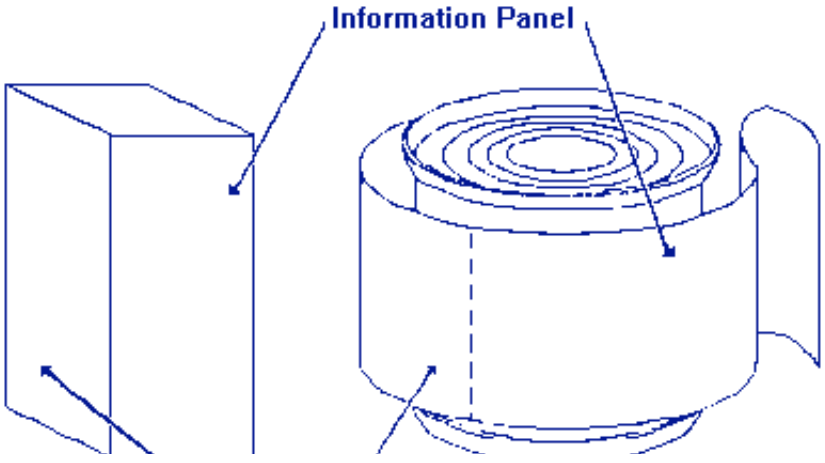
21 CFR 101.1

3. What label statements must appear on the PDP?



Answer: 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 IV and V of this guidance and 21 CFR 101.3(a) and 21 CFR 101.105(a)

4. Which label panel is the information panel?

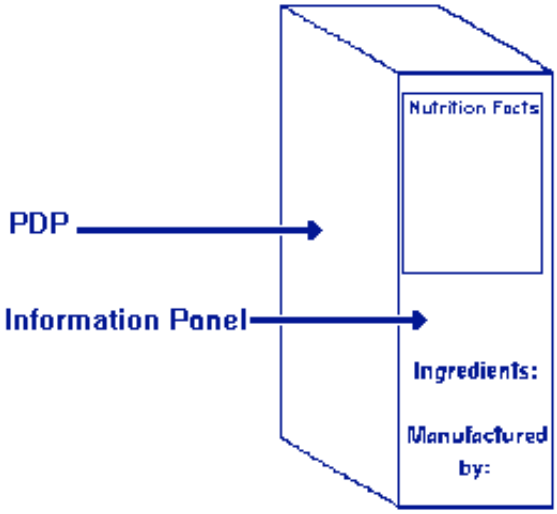


Answer: The information panel is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (e.g., folded flaps), then the

information panel is the next label panel immediately to the right.

21 CFR 101.2(a)

5. What is information panel labeling?



Answer: 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?

Answer: 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.

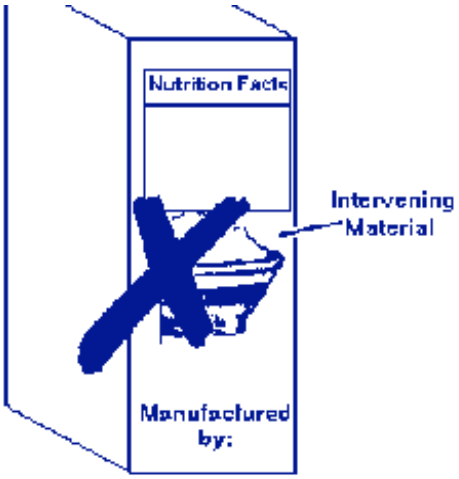
The type size requirements for the statement of identity and the net quantity statement are discussed in section V of this guidance.

21 CFR 101.2(c) and 21 CFR 101.9(d)(1)(iii)

7. What is the prohibition against intervening material?

Answer: 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).

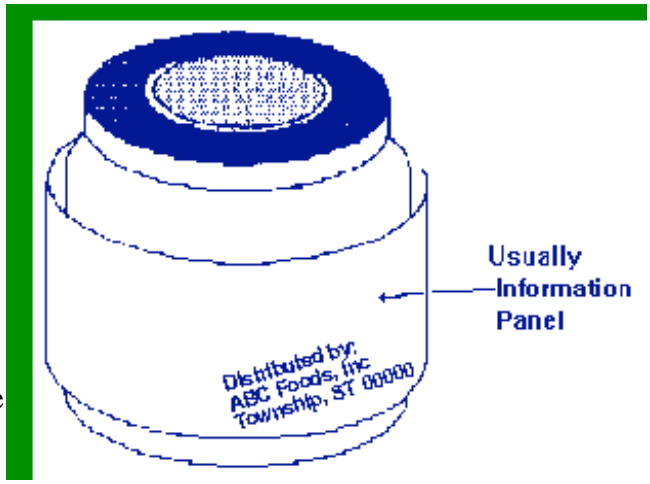
21 CFR 101.2(e)



8. What name and address must be listed on the label?

Answer: Food labels must list:

a. Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for "or "distributed by").



b. Street address if the firm name and address are not listed in a current city directory or telephone book;
c. City or town;
d. State (or country, if outside the United States); and
e. ZIP code (or mailing code used in countries other than the United States).

21 CFR 101.5

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Chapter IV. Name of Food

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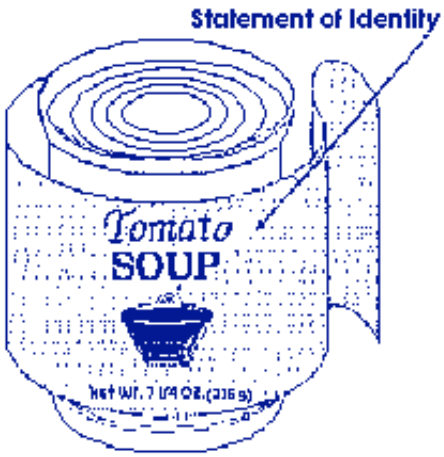
1. What is the name of the food statement called and where must it be placed?

Answer: The statement of identity is the name of the food. It must appear on the front label, or PDP as well as any alternate PDP. 21 CFR 101.3

2. Should the statement of identity stand out?



Answer: 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 PDP. 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?

Answer: The name established by law or regulation, or in the absence thereof, 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?

Answer: Place the statement of identity in lines generally parallel to the base of the package. 21 CFR 101.3(d)

5. When are fanciful names permitted as the statement of identity?

Answer: 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?

Answer: 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?

Answer: 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"?

Answer: Generally a new food that resembles a traditional food and is a substitute for the traditional food must be labeled as an imitation if the new food contains less protein or a lesser amount of any essential vitamin or mineral.

21 CFR 101.3(e)

9. What type size and degree of prominence is required for the word "imitation" in the product name?

Answer: 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. Are there restrictions on label artwork?

Answer: 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), 21 CFR 101.3(a), 21 CFR 101.105(h)

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

Answer: The law does not specifically require that the country of origin statement be placed on the PDP, 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. (FDA/CBP (Customs and Border Protection) Guidance and Customs regulation 19 CFR 134)

12. Are foreign language labels permitted?

Answer: 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)

Juices

J1. What causes a juice beverage label to be required to have a % juice declaration?

Answer: 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)

J2. Where and how is % juice declared?

Answer: The % juice must be on the information panel (for packages with information panels), 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"). If the package does not contain an information panel, the percent juice must be placed on the PDP in a type size not less than that required for the net contents declaration and placed near the name of the food. 21 CFR 101.30(e); 21 CFR 101.30(g)

J3. Are there any exceptions from the % juice requirement?

Answer: 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)

J4. How is the % juice calculated?

Answer: For juice expressed directly from fruit or vegetables: Compute on a volume/volume basis.

For 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), 21 CFR 101.30(h)

J5. Should my product be labeled as a "drink" or a "beverage?"

Answer: 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)

J6. Is it necessary to use the term "concentrate" on the label?

Answer: 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)

J7. What name is used on a mixed fruit or vegetable juice beverage?

Answer: When stated, names of juices (except in the ingredient list) must be in descending order of predominance by *volume*, unless the label indicates that the named juice is used as a flavor. Examples:

"Apple, Pear and Raspberry Juice Drink"
"Raspberry-Flavored Apple and Pear Juice Drink"

If the label represents one or more but not all the juices (except in the ingredient list), then the name must indicate that more juices are present. Examples:

"Apple Juice Blend"
"Apple Juice in a Blend of Two Other Fruit Juices"

When one or more, but not all, juices are named and the named juice is not the predominant juice, the name of the beverage must either state that the beverage is flavored with the named juice or declare the amount of the named juice in a 5% range. Examples (for a "raspcranberry" beverage that is primarily white grape juice with

raspberry and cranberry juices added):

"Raspcranberry Raspberry and Cranberry flavored Juice Drink"
"Raspcranberry Cranberry and Raspberry Juice Beverage
"10-15% Cranberry Juice and 3-8% Raspberry Juice"

21 CFR 102.33(b), 21 CFR 102.33(c), 21 CFR 102.33(d)

J8. What type sizes must be used in naming juices?

Answer: 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 PDP, and not less than 1/8 inch in height on packages with a PDP greater than 5 sq. in.

21 CFR 102.5(b)(2), 21 CFR 102.33(d), 21 CFR 102.33(g)

J9. When does a beverage purport to contain a fruit or vegetable juice?

Answer: Under 21 CFR 101.30(a), a beverage purports to contain fruit or vegetable juice if the product's advertising, label, or labeling, bears the name of, or makes any other direct or indirect representation with respect to any fruit or vegetable juice, or the label or labeling bears any vignette (i.e., depiction of a fruit or vegetable) or another pictorial representation of any fruit or vegetable, or product contains color and flavor that gives the appearance and taste of a fruit or vegetable juice. The beverages may be carbonated or noncarbonated, full strength, diluted, or contain no juice.

J10. Are bar mixes required to bear percent juice declarations under 21 CFR 101.30?

Answer: Bar mixes are subject to the same requirements as other beverage products. Thus, a percent juice declaration would be required on labels of bar mixes that meet the definition set out in 21 CFR 101.30(a).

J11. Is a whiskey sour mix that contains lemon juice from concentrate as the only juice component and a number of juice flavors and other ingredients, and that makes no claim or bears no pictures of fruits/fruit juices on the label required to bear a percent juice declaration?

Answer: No. A percent juice declaration would not be required on the whiskey sour mix if the only reference to the lemon juice is in the ingredient statement and no pictures of fruits/fruit juice appear on the label or in its labeling.

J12. Would a strawberry daiquiri mix have to bear a percent juice declaration?

Answer: A strawberry daiquiri mix would purport to contain strawberries or strawberry juice because the term "strawberry" appears in the identity statement. Also, there is no indication that the strawberry is present only as a flavor or flavoring. If its label or

labeling also includes pictures of the juice dripping from strawberries or if the product looks and tastes like it contains strawberry juice or strawberry pulp, the product would have to bear a declaration of the percent of juice or the absence of such juice on the information panel of the label. However, if the product were labeled "Strawberry flavored daiquiri mix " and did not otherwise purport to contain strawberry juice, it would not need a percent juice declaration.

J13. Must bloody mary mix bear a percent juice declaration?

Answer: Bloody mary mix, by appearance and taste, purports to contain tomato juice and thus would be required to bear a statement as to the percentage of juice contained in the product.

J14. Would a beverage that is made by reconstituting a blend of dehydrated fruits or vegetables be required to bear a percent juice declaration? If so, how is the percentage determined?

Answer: The declaration is required if the product purports to contain juice. However, because FDA has not established specific procedures for calculating the percentage of juice when beverages are prepared by rehydrating juice solids, it will evaluate labels of products made by this process on a case by case basis. Brix values, where provided in 21 CFR 101.30(h), may be used as guidelines in calculating the level of total juice solids necessary to prepare full strength juices, provided the beverage does not contain other non-juice ingredients.

J15. Do lemon and lime juices, used for mixed drinks, have to bear a percent juice declaration?

Answer: Yes. The percentage juice declaration would be based on the anhydrous citric acid content of the lemon juice or lime juice, listed in 21 CFR 101.30(h)(1).

J16. Is apple cider required to bear a percent juice declaration?

Answer: Apple cider is juice that is expressed from apples and must bear a declaration of the percent of juice.

J17. Does apple cider vinegar have to bear a percent juice declaration?

Answer: No. Apple cider vinegar does not purport to be a beverage and thus is not required to bear a percent juice declaration. Although the product is made from apple juice, it is not considered to be a juice beverage.

J18. Must concentrated juices bear percent declarations? If so what percentage is to be declared?

Answer: Concentrated juice products must bear a percentage juice declaration and that declaration may not be greater than 100 percent. The label may explain that when the product is diluted according to label directions, the product yields a "___percent juice

from concentrate," with the blank being filled in with the correct percentage based on the Brix values set out in 21 CFR 101.30(h)(1), as applicable.

J19. Is there an exemption from the requirement that the percent juice declaration be on the information panel for multi-unit packages that are packed in a secure shrink wrap and are not for sale by individual unit, and the percentage of juice is declared on the outer shrink wrap?

Answer: No, there is no specific exemption from the requirement that the percent juice declaration be on the information panel of individual juice packages packed in a multi-unit shrink wrap pack.

J20. Must the entire common or usual name of a juice beverage be in one place and in a single type size? Some juice beverages will have very complex common or usual names, like "cranberry-raspberry flavored juice drink in a blend of three other juices from concentrate."

Answer: The entire common or usual name must be in one place. If some or all of the juices listed in the name are from concentrate, the term "from concentrate" must follow the names and may be in a smaller type size, but not less than one half the height of the letters in the other part of the common or usual name.

J21. Regarding vignettes on juice labels, do the pictures have to be proportional to the fruits in the juice? Does any fruit that is present at a level of less than 2 percent by volume have to be depicted in the vignette?

Answer: FDA has not established specific requirements for vignettes on labels of juice beverages. FDA urges manufacturers to use vignettes that accurately depict each fruit or vegetable contained in the multiple juice products. However, a vignette depicting only some of the fruits or vegetables may not be considered misleading, if the name of the food adequately and appropriately describes the contribution of the pictured juice. For example, a 100 percent juice consisting of apple, grape and raspberry juices, in which raspberry juice provides the characterizing flavor, and bears a vignette that only depicts raspberries, would not necessarily be misleading if the identity statement were "raspberry juice blended with apple and grape juices." Alternatively, the statement of identity may be "raspberry flavored fruit juice blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice" (58 FR 2897 at 2921).

J22. Do I make any adjustments to the analytical Brix value in declaring the percentage of juice when tomato juice contains added salt or other dry ingredients (e.g., spices)?

Answer: Yes. The soluble solids content for tomato juice must be determined before addition of any spices. The soluble solids for tomato juice, determined by refractometer, should be corrected for salt content as prescribed in 21 CFR 156.3(b) and (c).

J23. I want to make a PDP statement "100 percent juice," and I have another ingredient (ascorbic acid) that does not dilute the juice solids. It appears that this is a nutrient content claim as well and I will have to meet all the requirements for "more" vitamin C,

including the comparison statements, and fortification policy. Have I understood correctly?

Answer: If ascorbic acid is added at levels consistent with fortification of the juice, its declaration in the name of the 100 percent juice would constitute a nutrition claim, triggering compliance with the "more" claim for vitamin C and the comparison statements. However, it is not necessary to specifically list the added ingredient by name in the 100 percent juice statement (i.e., the statement of identity could be "100 percent ___juice with preservative"). In this case the ascorbic acid would be added as a chemical preservative and listed by name in the ingredient statement in accordance with 21 CFR 101.22(j).

J24. Do I have to say "fruit punch from concentrate" or "lemonade from concentrate"?

Answer: No. Section 102.33(g) states that if one or more of the juices in a juice beverage is made from concentrate, then the name of the juice must include the term "from concentrate" or "reconstituted." Because the names "fruit punch" and "lemonade" do not include the name of a specific juice, these names do not have to contain the term "from concentrate" or reconstituted."

J25. Is the declaration on a lemonade made in terms of the lemon juice only, exclusive of sugar?

Answer: Yes, before adding sugar.

J26. We have a juice product for food service only, and we are exempt from nutrition labeling for this product (we know that is never goes to club stores). Are we also exempt from percent juice declarations?

Answer: No. There are no exemptions from the requirement for label declaration of the percentage of juice on food service containers of juices.

J27. Is the common or usual name regulation in 21 CFR 102.33 applicable to 100 percent juices or only to diluted juices?

Answer: The regulation is applicable to both.

J28. We have very small labels, about 7 square inches. How do you name a citrus punch which contains five juices in which three are from concentrate and two are expressed juices, and the expressed juices are not citrus juices nor do their flavors characterize the beverage? Also, what if one of the citrus juices is an expressed juice and is present only in a minor amount, must it be identified by name?

Answer: There are several alternatives. In the first case, the common or usual name may be "a blend of 3 citrus juices from concentrate with _____ and ____juices", the blanks filled in with names of the expressed juices. In the second case, the citrus juice that is not from concentrate should be listed as in the example given above in order of predominance, i.e., a blend of 2 citrus juices from concentrate with _____, _____, and

_____juices, with the third citrus juice listed in one of the blanks, along with the other expressed juices. Alternatively, a name such as "citrus punch" or "citrus flavored punch" may be used as the statement of identity without further identification of the component juices.

J29. Is it necessary to state that juices are from concentrate when they are contained in a beverage such as punch?

Answer: Yes, sometimes. If the juices are specifically named in the statement of identity, and the juices are from concentrate, their names must be followed by the term "from concentrate" in accordance with 21 CFR 102.33(g). If no reference is made to specific juices in the name of a punch that is made from concentrated juices, the statement of identity does not have to include the term "from concentrate." However, each of the concentrated juices used in the punch must be declared in order of predominance in the ingredient statement of the label.

J30. Does a punch have to be made from fruit juice?

Answer: No. FDA does not have a specific definition or standard of identity for punch, or any other requirement that a punch contain fruit juice. A punch may be an artificially flavored beverage, with or without natural flavorings, or it may be made from tea and other ingredients, exclusive of fruit juice. Such products must be clearly distinguished from products which are made from fruit juices or fruit concentrates or purees. Products containing artificial or natural flavors must be labeled in accordance with 21 CFR 101.22.

J31. In the case of a vegetable juice cocktail that is 100 percent juice, can the name include the term "cocktail"?

Answer: Yes.

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Chapter V. Net Quantity of Contents Statements

Contains Nonbinding Recommendations

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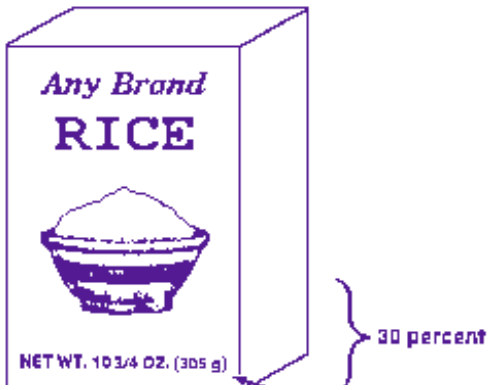
1. What is the net quantity of contents?

Answer: 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?

Answer: 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(e); 21 CFR 101.105(f)

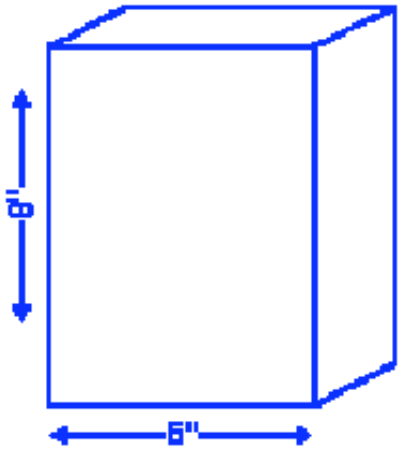
3. Should the net quantity of contents be stated in both grams and ounces?

Answer: Food labels printed must show the net contents in both metric (grams, kilograms, milliliters, liters) and U.S. Customary System (ounces, pounds, fluid ounces) terms. The metric statement may be placed either before or after the U. S. Customary statement, or above or below it. Each of the following examples is correct (additional examples appear in the regulations):

- Net wt 1 lb 8 oz (680g)
- Net wt 1 lb 8 oz 680 g
- 500 ml (1 pt 0.9 fl oz)
- Net contents 1 gal (3.79 L)

P.L. 102-329, August 3, 1992; 21 CFR 101.105

4. Why is it necessary to calculate the area of the PDP?

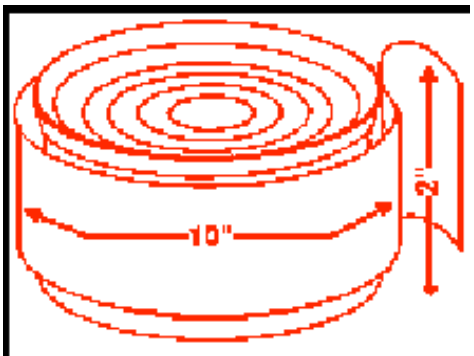


Area of PDP = 6" x 8" = 48 sq. in.

Answer: The area of the PDP (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 PDP as follows. The area of a rectangular or square PDP on a carton is the height multiplied by the width (both in inches or both in centimeters).

To calculate the area of the PDP for a cylindrical container, use 40% of the product of the height by the circumference. 21 CFR 101.1



10" x 2" = 20 sq. in.
Area of PDP = 20 sq. in. x 40%
= 8 sq. in.

5. What is the minimum type size?

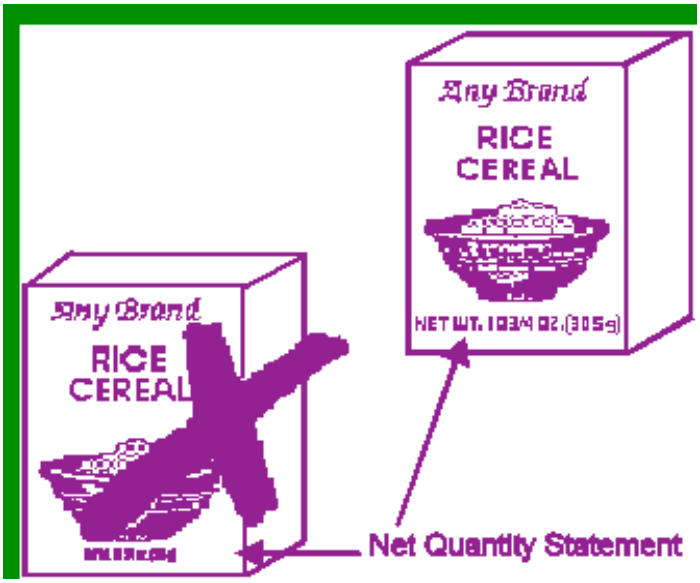
Answer: For the net quantity statements, the minimum type size is the smallest type size that is permitted based on the space available for labeling on the PDP. Determine the height of the type by measuring the height of the lower case letter "o" or its equivalent when mixed upper and lower case letters are used, or the height of the upper case letters when only upper case letters are used.

Minimum Type Size	Area of Principal Display Panel
1/16 in. (1.6 mm)	5 sq. in. (32 sq. cm.) or less
1/8 in. (3.2 mm)	More than 5 sq. in. (32 sq. cm.) but not more than 25 sq. in. (161 sq. cm.)
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?

Answer: 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?

Answer: Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food.

Filled container weighs	18 oz.
Empty container weighs	2 oz.
Wrapper weighs	1 oz.
Net Weight	**15 oz. (425 g)**

21 CFR 101.105(g)

8. Is water or other packing medium included in determining the net quantity of contents in a food container?

Answer: The water or other liquid added to food in a container is usually included in the net quantity declared on a label.

Beans weigh	9 oz.
Water weighs	4 oz.
Sugar weighs	1 oz.
Net Weight	**14 oz. (396 g)**

In some cases where the packing medium is normally discarded, the drained weight is given (e.g., olives and mushrooms).

21 CFR 101.105(a)

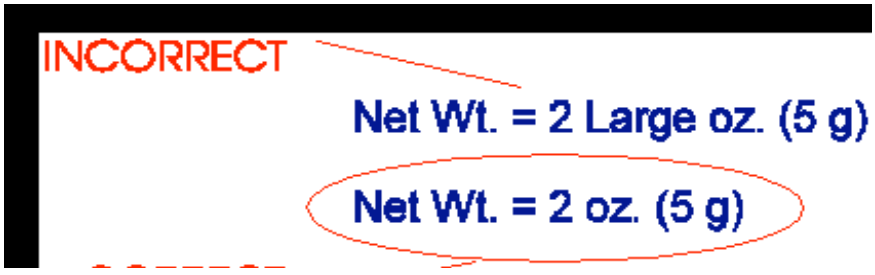
9. What is the net quantity of contents for a pressurized can?

Answer: 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?



Answer: Do not use qualifying phrases or terms that exaggerate

the amount of food. 21 CFR 101.105(o) ■ CORRECT

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FDA/Center for Food Safety & Applied Nutrition
Hypertext updated by cjm April 3, 2008

CFSAN/Office of Nutrition, Labeling, and Dietary Supplements
April 2008

Guidance for Industry

A Food Labeling Guide

Chapter VI. Ingredient Lists

Contains Nonbinding Recommendations

1. What is the ingredient list?
2. What is meant by the requirement to list ingredients in descending order of

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1. What is the ingredient list?

Answer: 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 by weight?

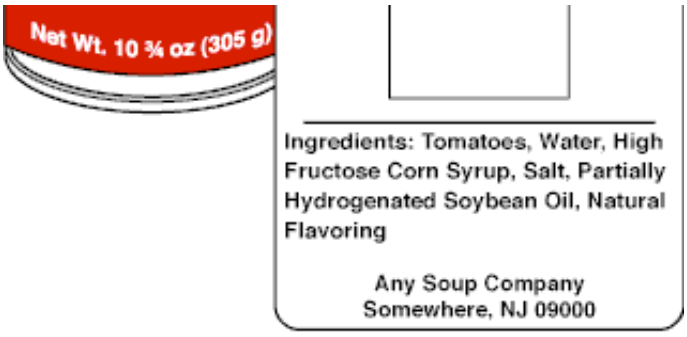
Answer: Listing ingredients in descending order of predominance by weight means that the ingredient that weighs the most is listed first, and the ingredient that weighs the least is listed last (see illustration for question 3 below). 21 CFR 101.4(a)

3. Where is the ingredient list placed on the label?

Answer: 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 PDP. It may be before or after the nutrition label and the name and address of the manufacturer, packer or distributor. 21 CFR 101.4

See also III Q7 of this guidance for information on intervening material on the information panel.



4. What type size is required for ingredient lists?

Answer: Use a type size that is at least 1/16 inch in height (based on the 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 III Q3 of this guidance. 21 CFR 101.2(c)

5. Should water be listed as an ingredient?

Answer: 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. If all water added during processing is subsequently removed by baking or some other means during processing, water need not be declared as an ingredient.

"INGREDIENTS: Water, Navy Beans, and Salt"

21 CFR 101.4(a); 21 CFR 101.4(c); Compliance Policy Guide 555.875

6. Should the common or usual name always be used for ingredients?

Answer: 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?

Answer: 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?

Answer: Listing alternative fat and oil ingredients ("and/or" labeling) in parentheses following the declaration of fat and oil blends 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?

Answer: When an approved chemical preservative is added to a food, the ingredient list must include both the common or usual name of the preservative and the function of the preservative by including terms, such as "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor," or "to promote color retention."

"INGREDIENTS: Dried Bananas, Sugar, Salt, and Ascorbic Acid to Promote Color Retention"

21 CFR 101.22(j)

10. How are spices, natural flavors or artificial flavors declared in ingredient lists?

Answer: 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. If fruit is canned in juice from concentrate, does the water used to reconstitute the juice have to be declared?

Answer: Yes. The reconstituted juice in which the fruit is canned is prepared from juice concentrate and water, thus both ingredients have to be declared.

12. Can juice concentrates be grouped in the ingredient statement (e.g., Fruit Juice Concentrates (grape, apple, cherry))?

Answer: No. "Fruit juice concentrates" is not established as a common or usual name, nor is it established as an appropriate collective name for a variety of different concentrated fruit juices.

13. When do you declare water as an ingredient in tomato concentrate?

Answer: Water that is added to adjust the Brix level of the standardized food within the permitted range of soluble solids (e.g., water used to adjust a Brix of 28° to 24° in tomato paste, or to adjust a Brix of 16° to 10° in tomato puree) does not have to be declared. However, water added to tomato paste (Brix of 24°) to make a product with a Brix of 16° (tomato puree) would have to be declared.

14. Can tomato paste, tomato puree, and tomato concentrate be used interchangeably in the ingredient statement?

Answer: Tomato paste and tomato puree are different foods based on the amount of soluble solids present in the product, and thus, the names can not be used interchangeably in the ingredient statement. However, the term "tomato concentrate" may be used in lieu of tomato paste, tomato pulp, or tomato puree when the concentrate complies with the requirements of such foods and the statement "for remanufacturing purposes only" appears on the label of packages equal to or less than 3.1 kilograms or 109 oz. Further, tomato concentrate may be used in lieu of tomato paste, tomato pulp, or tomato puree in the ingredient labeling of catsup.

15. Do ingredients of standardized foods have to be listed when the standardized food is an ingredient in a non-standardized food?

Answer: Yes. The ingredients of the standardized food may be declared parenthetically following the name of the standardized ingredient or may be declared by dispersing each ingredient in its order of predominance in the ingredient statement without naming the standardized food.

16. Do you have to parenthetically declare all of the ingredients in flavors that conform to a standard of identity?

Answer: If the flavor is declared by the standardized name, each ingredient must also be declared parenthetically following the standardized name. However, the standardized flavor may simply be declared as flavoring, natural flavoring, artificial flavoring, as appropriate.

17. How do you declare protein hydrolysates that are made of blends of proteins?

Answer: For proteins that are blended prior to being hydrolyzed an appropriate name for the hydrolyzed protein product must be sufficiently descriptive of the protein product and must include all of the various proteins that were used to make the hydrolyzed protein. For example a hydrolyzed protein made from a blend of corn and soy protein would be "hydrolyzed corn and soy protein." However, if the proteins are hydrolyzed prior to blending, then the common or usual name must be specific to each individual hydrolyzed protein (e.g., "hydrolyzed corn protein" and "hydrolyzed soy protein"), and the ingredients must be declared in their order of predominance. In addition, any other ingredients that are blended with the hydrolyzed protein products must also be declared by their common or usual names in the ingredient statement in order of predominance.

Colors

C1. What ingredient listing is used for vegetable powder?

Answer: Vegetable powders must be declared by common or usual name, such as "celery powder." 21 CFR 101.22(h)(3)

C2. What listing is used for a spice that is also a coloring?

Answer: 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)

C3. What ingredient listing is used for artificial colors?

Answer: 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 "colored with beet juice."

21 CFR 101.22(k)(1) and (2), 21 CFR 74

C4. Do certified color additive lakes have to be declared separately from the certified color in the ingredient statement?

Answer: Yes. Certified color additives and their lakes are separate ingredients and, thus, must be declared separately in the ingredient statement.

Food Allergen Labeling

General Information

F1. What is the Food Allergen Labeling and Consumer Protection Act of 2004?

Answer: The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (or Title II of Public Law 108-282) is a law that was enacted in August 2004. Among other issues, FALCPA addresses the labeling of all packaged foods regulated by the FDA. We recommend that producers of meat products, poultry products, and egg products, which are regulated by the U.S. Department of Agriculture (USDA), contact appropriate USDA agency staff regarding the labeling of such products. Also see Information about Food Allergens for more information about the agency's food allergen activities and related guidance documents that address additional FALCPA questions and answers.

F2. What is a "major food allergen?"

Answer: Under FALCPA, a "major food allergen" is an ingredient that is one of the following eight foods or food groups or an ingredient that contains protein derived from one of them:

a. milk
b. egg
c. fish
d. Crustacean shellfish
e. tree nuts
f. wheat
g. peanuts
h. soybeans

Although more than 160 foods have been identified to cause food allergies in sensitive individuals, the "major food allergens" account for 90 percent of all food allergies. Allergens other than the major food allergens are not subject to FALCPA labeling requirements.

F3. When did the labeling requirements of the FALCPA become effective for packaged foods sold in the United States?

Answer: All packaged foods regulated by FDA under the FD&C Act that are labeled on or after January 1, 2006, must comply with FALCPA's food allergen labeling requirements.

F4. Are flavors, colors, and incidental additives subject to FALCPA labeling requirements?

Answer: Yes. FALCPA labeling requirements apply to foods that are made with any ingredient, including flavorings, colorings, or incidental additives (e.g., processing aids), that is or contains a major food allergen.

F5. Do retail and foodservice establishments have to comply with FALCPA's labeling requirements?

Answer: FALCPA's labeling requirements extend to foods packaged by a retail or foodservice establishment that are offered for human consumption. However, FALCPA's labeling requirements do not apply to foods provided by a retail food establishment that are placed in a wrapper or container in response to a consumer's order - such as the paper or box used to convey a sandwich that has been prepared in response to a consumer's order.

Foods Not Subject To FALCPA

F6. Are there any foods exempt from FALCPA labeling requirements?

Answer: Yes. Under FALCPA, raw agricultural commodities (generally fresh fruits and

vegetables) are exempt as are highly refined oils derived from one of the eight major food allergens and any ingredient derived from such highly refined oil. In addition, FALCPA provides mechanisms by which a manufacturer may request that a food ingredient may be exempt from FALCPA's labeling requirements. See FALCPA Section 203 for details on how to request allergen labeling exemptions.

F7. Are molluscan shellfish considered a major food allergen under FALCPA?

Answer: No. Under FALCPA, molluscan shellfish (e.g., such as oysters, clams, mussels, or scallops) are not major food allergens. However, Crustacean shellfish (e.g., crab, lobster, or shrimp), and ingredients that contain protein derived from Crustacean shellfish, are major food allergens.

Major Food Allergens (food source names and examples)

F8. Does FALCPA provide any specific direction for declaring the presence of ingredients from the three food groups that are designated as "major food allergens (i.e., tree nuts, fish, and Crustacean shellfish)"?

Answer: Yes. FALCPA requires that in the case of tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts). The species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).

F9. Under Section 403(w)(1) of the FD&C Act, a major food allergen must be declared using the name of the food source from which the major food allergen is derived. Section 403(w)(2) of the FD&C Act provides that, in the case of fish or Crustacean shellfish, the term "name of the food source from which the major food allergen is derived" means the "species" of fish or Crustacean shellfish. What is the "species" of fish or Crustacean shellfish for purposes of Section 403(w)(2)?

Answer: A declaration of the "species" of fish or Crustacean shellfish for purposes of complying with Section 403(w)(2) should be made using the acceptable market name provided in FDA's *The Seafood List*. *The Seafood List* is a compilation of existing acceptable market names for imported and domestically available seafood.

F10. Section 201(qq) of the FD&C Act defines the term "major food allergen" to include "tree nuts." In addition to the three examples provided in section 201(qq) (almonds, pecans, and walnuts), what nuts are considered "tree nuts?"

Answer: The following are considered "tree nuts" for purposes of section 201(qq). The name listed as "common or usual name" should be used to declare the specific type of nut as required by section 403(w)(2).

Common or usual name	Scientific name
Almond	*Prunus dulcis* (Rosaceae)

Beech nut	*Fagus* spp. (Fagaceae)
Brazil nut	*Bertholletia excelsa* (Lecythidaceae)
Butternut	*Juglans cinerea* (Juglandaceae)
Cashew	*Anacardium occidentale* (Anacardiaceae)
Chestnut (Chinese, American, European, Seguin)	*Castanea* spp. (Fagaceae)
Chinquapin	*Castanea pumila* (Fagaceae)
Coconut	*Cocos nucifera* L. (Arecaceae (alt. Palmae)
Filbert/hazelnut	*Corylus* spp. (Betulaceae)
Ginko nut	*Ginkgo biloba* L. (Ginkgoaceae)
Hickory nut	*Carya* spp. (Juglandaceae)
Lichee nut	*Litchi chinensis* Sonn. Sapindaceae
Macadamia nut/Bush nut	*Macadamia* spp. (Proteaceae)
Pecan	*Carya illinoensis* (Juglandaceae)
Pine nut/Pinon nut	*Pinus* spp. (Pineaceae)
Pistachio	*Pistacia vera* L. (Anacardiaceae)
Sheanut	*Vitellaria paradoxa* C.F. Gaertn. (Sapotaceae)
Walnut (English, Persian, Black, Japanese, California), Heartnut	*Juglans* spp. (Juglandaceae),

The foregoing list reflects FDA's current best judgment as to those nuts that are "tree nuts" within the meaning of Section 201(qq). In order to be comprehensive, this list employs broad scientific categories that may include a species that currently has no food use. The fact that a species falls within a scientific category on this list does not mean that the species is appropriate for food use. FDA further advises that, as with any guidance, the list may be revised consistent with the process for revising guidance documents in our regulation on good guidance practices in 21 CFR 10.115.

F11. Section 201(qq) of the FD&C Act includes "wheat" in the definition of major food allergen. What is considered "wheat" for purposes of Section 201(qq)?

Answer: The term "wheat" in Section 201(qq) means any species in the genus *Triticum*. Thus, for the purposes of Section 201(qq), wheat would include grains such as common wheat *(Triticum aestivum L.)*, durum wheat *(Triticum durum Desf.)*, club wheat *(Triticum compactum Host.)*, spelt *(Triticum spelta L.)*, semolina *(Triticum durum Desf.)*, Einkorn *(Triticum monococcum L. subsp. Monococcum)*, emmer *(Triticum turgidum*L. subsp. *dicoccon* (Schrank) Thell.), kamut *(Triticum polonicum* L.), and triticale (x *Triticosecale* ssp. Wittm.).

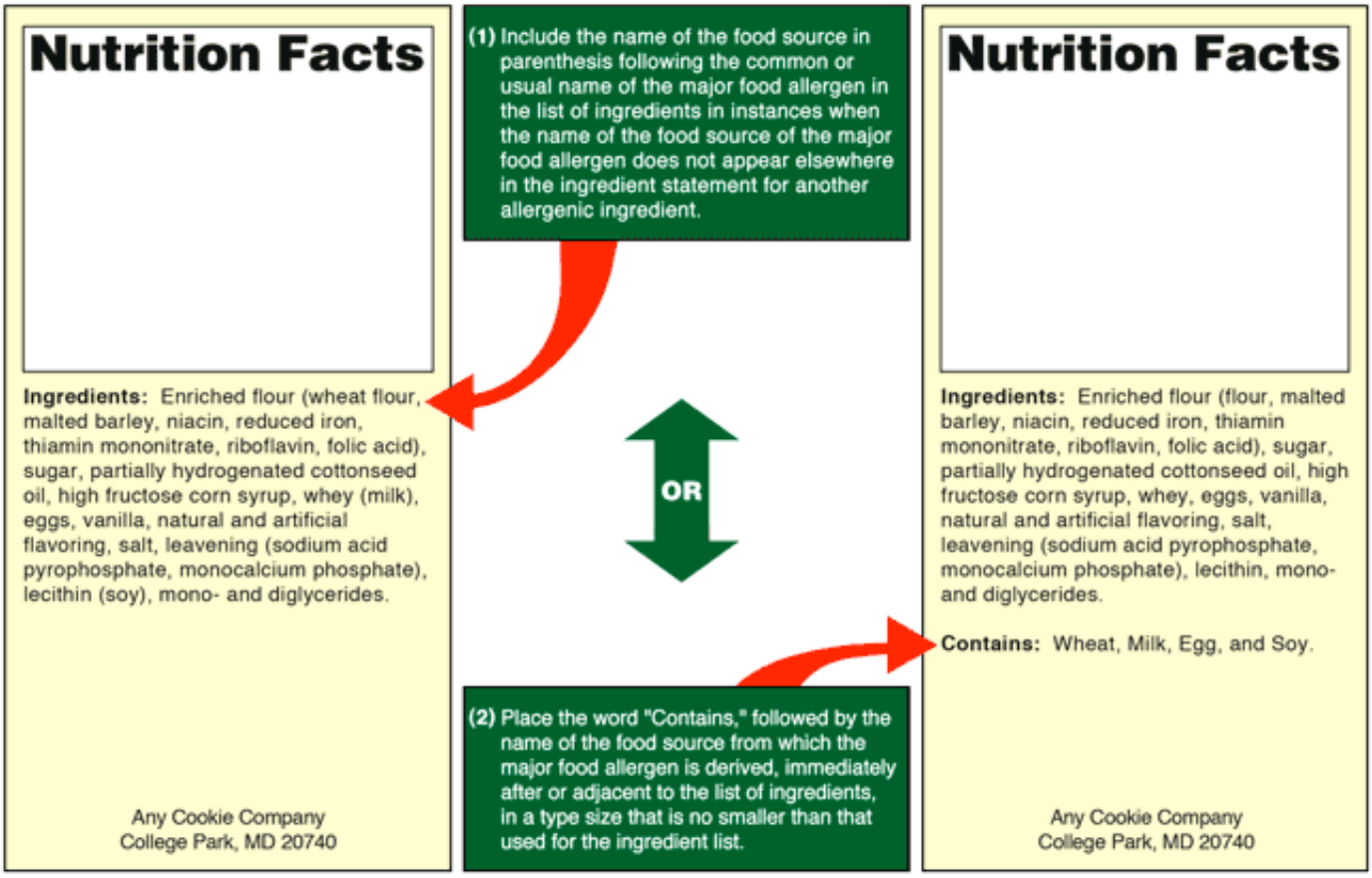
F12. May singular terms be substituted for the plural terms "peanuts," "soybeans" and the different types of "tree nuts" (e.g., almonds, pecans, or walnuts), and may synonyms for the term "soybean" be used to satisfy the labeling requirements of FALCPA?

Answer: Yes. FDA believes that the singular terms "peanut," and "soybean," as well as the singular terms (e.g., almond, pecan, or walnut) for the different types of tree nuts are acceptable substitutes for the plural terms for these major food allergens for the purpose of satisfying the FALCPA labeling requirements. Also, the terms "soybean," "soy," and "soya" are reasonable synonyms for the common or usual name "soybeans," and any one of these terms may be used to identify the food source of the major food allergen "soybeans." However, packaged foods that are made using "soybeans" as an ingredient or as a component of a multi-component ingredient (e.g., soy sauce or tofu) should continue to use the word "soybeans" as the appropriate common or usual name for this ingredient to identify properly the ingredient (e.g., "soy sauce (water, wheat, soybeans, salt)").

FALCPA Labeling (provisions and examples)

F13. How must major food allergens be declared on food labels to comply with FALCPA?

Answer: FALCPA requires food manufacturers to label food products that are made with an ingredient that is a major food allergen in *one* of the following two ways:



F14. Are single ingredient foods that are major food allergens required to comply with FALCPA?

Answer: Yes. Single ingredient foods must comply with the allergen declaration requirements in Section 403(w)(1). A single ingredient food that is, or contains protein derived from milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, or soybeans, may identify the food source in the name of the food (e.g., "all-purpose wheat flour") or use the "Contains" statement format. FDA recommends that if a "Contains" statement format is used, the statement be placed immediately above the manufacturer, packer, or distributor statement. For single ingredient foods intended for further manufacturing where the "Contains" statement format is used, the statement should be placed on the PDP of the food.

F15. May a "Contains" statement on a food label provided in accordance with FALCPA list only the names of the food sources of the major food allergens that are not already identified in the ingredient list for a packaged food?

Answer: No. If a "Contains" statement is used on a food label, the statement must include the names of the food sources of all major food allergens used as ingredients in the packaged food. For example, if "sodium caseinate," "whey," "egg yolks," and "natural peanut flavor" are declared in a product's ingredients list, any "Contains" statement appearing on the label immediately after or adjacent to that statement is required to identify all three sources of the major food allergens present (e.g., "Contains

milk, egg, peanuts") in the same type (i.e., print or font) size as that used for the ingredient list.

F16. Is there more than one way to word a "Contains" statement used to declare the major food allergens in a packaged food?

Answer: Yes. The wording for a "Contains" statement may be limited to just stating the word "Contains" followed by the names of the food sources of all major food allergens that either are or are contained in ingredients used to make the packaged product. Alternatively, additional wording may be used for a "Contains" statement to more accurately describe the presence of any major food allergens, provided that the following three conditions are met:

- The word "Contains" with a capital "C" must be the first word used to begin a "Contains" statement. (The use of bolded text and punctuation within a "Contains" statement is optional.)
- The names of the food sources of the major food allergens declared on the food label must be the same as those specified in the FALCPA, except that the names of food sources may be expressed using singular terms versus plural terms (e.g., walnut versus walnuts) and the synonyms "soy" and "soya" may be substituted for the food source name "soybeans."
- If included on a food label, the "Contains" statement must identify the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food.

CFSAN/Office of Nutrition, Labeling, and Dietary Supplements
April 2008

Guidance for Industry

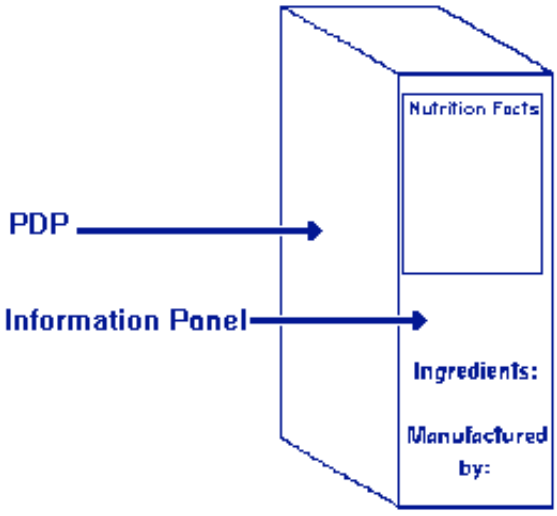
A Food Labeling Guide

VII. Nutrition Labeling

Contains Nonbinding Recommendations

General

G1. Where should the Nutrition Facts label be placed on food packages?



Answer: The Nutrition Facts label may be placed together with the ingredient list and the name and address (name and address of the manufacturer, packer, or distributor) on the PDP. These three label statements also may be placed on the information panel (the label panel adjacent and to the right of the PDP, or, if there is insufficient space on the adjacent panel, on the next adjacent panel to the right). On packages with insufficient area on the PDP and information panel, the Nutrition Facts label may be placed on any alternate panel that can be seen by the consumer.

G2. Is it necessary to use a nutrition display with a box shape on a round package?

Answer: Yes. Even when using the tabular display, the nutrition information must be set off in a box.

G3. Can the product name be placed within the Nutrition Facts label?

Answer: No. The name may be placed above the box that encloses the nutrition information.

G4. Can the Nutrition Facts label be oriented perpendicularly as opposed to parallel, to the base of the package?

Answer: Yes. There is no requirement that any information, other than the net quantity of contents and statement of identity, be printed parallel to the base of the package. However, FDA urges manufacturers to strive for consistency of presentation of nutrition information in the market and to place the Nutrition Facts label so that it is readily observable and legible to the consumer at the point of purchase.

G5. Is a break in the vertical alignment allowed with the standard format?

Answer: Yes. The vertical format may be broken in either of the following ways: (1) placement of the footnote to the right of the panel as shown in 21 CFR 101.9(d)(11) or (2) all vitamins and minerals that are listed voluntarily (i.e., after iron) may be moved to the top right of the panel along with the footnote.

Nutrient Declaration

N1. Are Nutrition Facts labels required on all foods?

Answer: The Nutrition Facts label (an example is illustrated in VII L2) is required on most food packages labeled. The illustration indicates FDA's typeface and style to help assure readibility and conspicuousness. Not all of these type specifications are required. The mandatory type specifications are listed in 21 CFR 101.9(d). Unlike the illustrative examples in this guidance, (1) Any legible type style may be used, not just Helvetica, (2) The heading Nutrition Facts must be the largest type size in the nutrition label (i.e., it must be larger than 8-point, but does not need to be 13-point), and (3) There is no specific thickness required for the three bars that separate the central sections of the nutrition label. 21 CFR 101.9(a) and 21 CFR 101.9(a)(1)

Below are listed categories providing exemptions or special provisions for nutrition labeling. A food package loses those exemptions, which are asterisked, if a nutrition claim is made or nutrition information is provided:

Summary of Exemption	Regulation #
*Manufactured by small businesses	21 CFR 101.9(j)(1) and 101.9(j)(18)
*Food served in restaurants, etc. or delivered to homes ready for immediate consumption	21 CFR 101.9(j)(2)
*Delicatessen-type food, bakery products	21 CFR 101.9(j)(3)

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	21 CFR 101.9(j)(4)
Infant formula, and infant and junior foods for children up to 4 years of age (modified label provisions for these categories)	21 CFR 101.9(j)(5) and 101.9(j)(7)
Dietary supplements (must comply with 21 CFR 101.36)	21 CFR 101.9(j)(6)
Medical foods	21 CFR 101.9(j)(8)
Bulk foods shipped for further processing or packaging before retail sale	21 CFR 101.9(j)(9)
*Fresh produce and seafood (a voluntary nutrition labeling program covers these foods through the use of the appropriate means such as shelf labels, signs, and posters)	21 CFR 101.9(j)(10) and 101.45
Packaged single-ingredient fish or game meat may be labeled on basis of 3-ounce cooked portion (as prepared). Custom-processed fish and game are exempt from nutrition labeling.	21 CFR 101.9(j)(11)
Certain egg cartons (nutrition information inside lid or on insert in carton)	21 CFR 101.9(j)(14)
Packages labeled "This unit not labeled for retail sale" within multiunit package, and outer wrapper bears all required label statements	21 CFR 101.9(j)(15)
Self-service bulk foods--nutrition labeling by placard, or on original container displayed clearly in view	21 CFR 101.9(a)(2) and 101.9(j)(16)
Donated food that is given free (not sold) to the consumer.	You are not required to put Nutrition Facts labels on donated food unless the donated food is later placed on sale (the law applies only to food that is "offered for sale") -- 21 CFR 101.9(a)
Game meats may provide required nutrition information or labeling in accordance with 21 CFR 101.9(a)(2).	21 CFR 101.9(j)(12)

N2. Are nutrition designations permitted on food package labels?

Answer: FDA considers information that is required or permitted in the Nutrition Facts label on the front label or elsewhere on the package to be a Nutrient Content Claim (NCC). In such cases, the package label must comply with the regulations for nutrient content claims. See the NCC section and Appendices A and B of this document for more information. 21 CFR 101.13(c)

N3. What other nutrients can be declared on the Nutrition Facts label?

Answer: In addition to the nutrients shown on the label in VII L2 manufacturers may add calories from saturated fat, polyunsaturated fat, monounsaturated fat, potassium, soluble and insoluble fiber, sugar alcohol, other carbohydrate, vitamins and minerals for which Reference Daily Intake (RDI's) have been established, or the percent of vitamin A that is present as beta-carotene. 21 CFR 101.9(c)

N4. Is there a restriction against certain nutrients in the Nutrition Facts label?

Answer: Only those nutrients listed in FDA's nutrition regulations, as mandatory or voluntary components of the nutrition label, may be included in the Nutrition Facts label. 21 CFR 101.9(c)

N5. When must voluntary nutrients be listed?

Answer: In addition to the nutrients shown on the sample labels in this guidance, other nutrients (listed in FDA's regulations, e.g., thiamin) must be included in a food's Nutrition Facts label if the nutrients are added as a nutrient supplement to the food, if the label makes a nutrition claim (such as a NCC) about them, or if advertising or product literature provides information connecting the nutrients to the food. 21 CFR 101.9(a), 21 CFR 101.9(c), 21 CFR 101.9(c)(8)(ii)

N6. When should the vitamins and minerals in flour be listed on the Nutrition Facts label?

Answer: Generally, FDA only requires that the label declare the vitamins A and C, and the minerals calcium and iron. The other enrichment vitamins and minerals must be declared when they are added directly to the packaged food (e.g., enriched bread), but not when the enriched product is added as an ingredient to another food. NOTE: It is necessary to declare the other vitamins and minerals in the ingredient list. However, if unenriched flour is used, and the enrichment nutrients are added separately, those nutrients (i.e., thiamin, riboflavin, niacin, and folic acid) would have to be declared on the Nutrition Facts label. 21 CFR 101.9(c)(8)(ii)(A)-(B) and 21 CFR 101.9(c)(8)(iv)

N7. When the caloric value for a serving of a food is less than 5 calories, can the actual caloric value be declared?

Answer: The caloric value of a product containing less than 5 calories may be expressed as zero or to the nearest 5 calorie increment (i.e., zero or 5 depending on the level).

Foods with less than 5 calories meet the definition of "calorie free" and any differences are dietarily insignificant.

N8. Should a value of 47 calories be rounded up to 50 calories or rounded down to 45 calories?

Answer: Calories must be shown as follows:

50 calories or less--Round to *nearest* 5-calorie increment:
Example: Round 47 calories to "45 calories"
Above 50 calories--Round to *nearest* 10-calorie increment:
Example: Round 96 calories to "100 calories"

21 CFR 101.9(c)(1)
Also see Appendix H for rounding guidelines.

N9. How are calories from alcohol to be calculated?

Answer: Calories from alcohol may be calculated using specific Atwater factors as provided for in 21 CFR 101.9(c)(1)(i)(A). USDA Handbook No. 74 provides a specific food factor of 7.07 calories per gram of alcohol.

N10. What is total fat?

Answer: To determine the total fat content of a food, add the weight in grams of all lipid fatty acids in the food (e.g., lauric, palmitic, stearic fatty acids) and express as triglycerides. Total fat = Weight of all individual fatty acids + weight of one unit of glycerol for each three fatty acids. 21 CFR 101.9(c)(2)

N11. Does total fat, which is defined as total lipid fatty acid expressed as triglycerides, include cholesterol?

Answer: No.

N12. The total fat content for a serving of my product is 0.1 g. How should I declare fat and calories from fat?

Answer: Because it is present at a level below 0.5 g, the level of fat is expressed as 0 g. Calories from fat would also be expressed as zero.

N13. What fractions are used for total fat on the Nutrition Facts label?

Answer: Below 0.5 grams total fat per serving: Use the declaration 0 grams for total fat. 0.5 grams to 5 grams total fat: Use ½ gram increments rounded to the nearest ½ gram.

Examples: 0.5 g, 1 g, 1.5 g, 2 g, 2.5 g, 3 g, 3.5 g, 4 g, 4.5 g, 5 g

Above 5 grams: Use 1 gram increments rounded to the nearest 1 gram (do not use fractions above 5 grams).

Examples: 5 g, 6 g, 7 g, etc.

21 CFR 101.9(c)(2)
Also see Appendix H for rounding guidelines.

N14. What values are used for calculating Daily Values for the nutrition label?

Answer: See Appendix F: Calculate the percent daily value (DV) for the appropriate nutrients and Appendix G: Daily Values for Infants, Children Less Than 4 Years of Age, and Pregnant and Lactating Women

N15. When less than 0.5 grams of dietary fiber or saturated fat is present in a serving of a product, the amounts would be shown as zero on the label. However, when the % DV is calculated based on an actual unrounded fiber or saturated fat content of 0.2 grams per serving, the calculation yields 1 percent. To avoid consumer confusion can the % DV be expressed as zero in these cases?

Answer: Yes. Section 101.9(d)(7)(ii) permits the percent Daily Value to be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the Daily Reference Value (DRV) for that nutrient except that the percent for protein must be calculated as specified in 21 CFR 101.9(c)(7)(ii). As a result of this change, whenever a declared quantitative amount is zero, the declared percent Daily Value will also be zero.

N16. How is total carbohydrate calculated?

Answer: Total carbohydrate is calculated by subtracting the weight of crude protein, total fat, moisture, and ash from the total weight ("wet weight") of the sample of food. 21 CFR 101.9(c)(6)

N17. Does total carbohydrate include dietary fiber?

Answer: Yes. Dietary fiber must be listed as a subcomponent under total carbohydrate.

N18. What is meant by sugars on the Nutrition Facts label?

Answer: To calculate sugars for the Nutrition Facts label, determine the weight in grams of all free monosaccharides and disaccharides in the sample of food. The other nutrients declared on the nutrition label are defined in 21 CFR 101.9(c). 21 CFR 101.9(c)(6)(ii)

N19. I have 0.8 grams of fiber in a serving of food. Can I round this up to 1 g, or must I use the statement "less than 1 g?" Can I do the same thing for protein?

Answer: Since this serving contains less than 1 gram of dietary fiber per serving, fiber is to be expressed as "Less than 1 gram" or "Contains less than 1 gram," or the manufacturer has the option to not list dietary fiber and include the following statement at the bottom of the table of nutrients: "Not a significant source of dietary fiber." Protein can be expressed to the nearest whole gram (i.e., 1 g); or the label can state "less than 1

gram" or "Contains less than 1 gram." The "<" symbol may be used in place of the words "less than" (21 CFR 101.9(d)(7)(i)).

N20. Under what circumstances is the listing of sugar alcohol required?

Answer: When a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food 21 CFR 101.9(c)(6)(iii).

N21. What DRV's and RDI's are established for protein for the purpose of listing protein as a percent of Daily Value (% DV)?

Answer: The DRV for protein for adults and children 4 or more years of age is 50 grams. The RDIs for protein for children less than 4 years of age, infants, pregnant women, and lactating women are established at 16 grams, 14 grams, 60 grams, and 65 grams respectively. 21 CFR 101.9(c)(7)(iii)

N22. Why is the declaration of the DRV for protein not mandatory?

Answer: The percent of the DRV is required if a protein claim is made for the product or if the product is represented or purported to be for use by infants or children under 4 years of age. Based on current scientific evidence that protein intake is not a public health concern for adults and children over 4 years of age, and because of the costs associated with a determination of the Protein Digestibility Corrected Amino Acid Score (PDCAAS), FDA has determined that declaration of the percent of the DRV for protein need not be provided when a claim is not made.

N23. How should the % DV for protein be expressed when it is provided on labeling of foods for adults and children over four?

Answer: When protein is listed as a percent of the 50 gram DRV and expressed as % DV, the % DV is calculated by correcting the actual amount of protein in grams per serving by multiplying the amount by its amino acid score corrected for protein digestibility, dividing by 50 grams, and converting to percent.

N24. When % DV's for protein and potassium are included on the Nutrition Facts label on foods for adults and children over 4 years, where in the footnote is the DRV information to be placed?

Answer: Protein should be listed in the footnote under dietary fiber with the DRV inserted on the same line in the numeric columns. The DRV for protein is based on 10 percent of calories as protein, which equates to 50 grams for a 2,000 calorie diet and 65 grams (62.5 rounded up to 65) for a 2,500 calorie diet. Similarly, potassium would be listed in the footnote under sodium. The DRV for potassium is 3,500 milligrams for both the 2,000 and 2,500 calorie diets.

N25. How do I determine what values to declare on the Nutrition Facts label?

Answer: The nutrient values declared on the Nutrition Facts label are based on the

nutrient profile of the product, as packaged, rounded as required by regulation. Rounding rules are provided in 21 CFR 101.9(c) and summarized in Appendix H.

N26. In what order must vitamins and minerals be declared?

Answer: Please refer to 21 CFR 101.9(c)(8)(iv).

N27. How should vitamins and minerals that are permitted to be listed voluntarily be listed?

Answer: If potassium is listed, it should be listed in bold type directly under sodium. Voluntary vitamins and minerals (i.e., those other than vitamin A, Vitamin C, Calcium, and Iron), should be declared horizontally or vertically following the required vitamins and minerals. 21 CFR 101.9(c)(5) and 21 CFR 101.9(d)(8)

N28. Is it legal to declare 400% of the Daily Value for a vitamin?

Answer: Yes. The percent Daily Value is based on the amount of the nutrient present in the product.

N29. Can information about nutrients that do not have an RDI/DRV such as boron and omega-3 fatty acids be provided on the food label?

Answer: Yes, provided that the information is truthful and not misleading and is provided outside the Nutrition Facts label. Such information is limited to statements of amount and may not characterize the level of the nutrient (e.g., can not state "High in Omega-3").

N30. Would a dry mix product such as flavored rice be required to provide nutrition information for both the product as packaged and as prepared?

Answer: Only the nutritional properties of the product as packaged is required. However, nutritional information may be voluntarily presented "as prepared" as provided for in 21 CFR 101.9(h)(4).

N31. Can I use "average" values derived from data bases to determine the nutrient content of my product?

Answer: FDA has not stated how a company should determine the nutrient content of their product for labeling purposes. Therefore, there is no prohibition from using "average" values for its product derived from data bases if a manufacturer is confident that the values obtained meet FDA's compliance criteria. Regardless of its source, a company is responsible for the accuracy and the compliance of the information presented on the label. Use of a data base that has been accepted by FDA affords a firm some measure of security in that the agency has stated that it will work with industry to resolve any compliance problems that might arise for food labeled on the basis of a data base that the agency has accepted. A manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases" is available online.

N32. How many samples of each product should we analyze for nutrition labeling?

Answer: FDA has not defined the number of samples that must be analyzed. It is the responsibility of the manufacturer/packer/distributor to determine the variability of their product(s) and the number of samples needed to provide accurate nutrient data. The "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases," available from FDA, may be of assistance in this area. FDA will use a composite of 12 units when performing enforcement analyses.

N33. May I copy my competitor's label?

Answer: Firms are responsible for the accuracy of the Nutrition Facts label and there is no assurance that the data from a competitor's product is valid for another product. Products of a similar nature are not necessarily equivalent in ingredients and nutrient value. If FDA found a product to be out of compliance because a firm merely copied its competitor's label, the firm would be hard pressed to prove that they labeled the product "in good faith."

N34. Will FDA analyze my products and send me a report to use for my nutrition label?

Answer: No. FDA does not have the resources to analyze products upon request. However, FDA will collect surveillance samples to monitor the accuracy of nutrition information. The manufacturer, packer or distributor would be advised of any analytical results that are not in compliance. Additionally, depending on circumstances, FDA may initiate regulatory action.

N35. Does FDA produce/provide data base information to industry?

Answer: No. FDA will review and accept industry data bases which remain the property of the organization that developed and submitted the data.

N36. Can FDA recommend an analytical laboratory and must a laboratory be approved to perform nutrient analysis?

Answer: FDA does not approve, and is not in a position to endorse or recommend, specific laboratories. Assistance may be available through the following sources: trade and professional associations, trade publications, colleges and universities, and by looking in local phone books under testing or analytical laboratories. For compliance purposes FDA uses appropriate methods published by the Association of Analytical Chemists (AOAC) in Official Methods of Analysis of the AOAC International, 18th edition (2005) EXIT disclaimer or other methods as needed. You may wish to ascertain if the laboratory is familiar with these methodologies when selecting a laboratory.

N37. How many samples must be analyzed to determine the nutrient levels for a product?

Answer: The number of samples to analyze for each nutrient is determined by the variability of each nutrient in a food. Fewer analytical samples are generally required for nutrients that are less variable. The variables that affect nutrient levels should be

determined, and a sampling plan should be developed to encompass these variables.

N38. Is there a problem with using ingredient composition data bases to calculate the values for nutrition labeling?

Answer: If manufacturers choose to use ingredient data bases, they should be assured of the accuracy of the databases and validate the resulting calculations by comparing them with values for the same foods obtained from laboratory analyses. Manufacturers are responsible for the accuracy of the nutrition labeling values on their products. Although FDA specifies the laboratory methods that will be used to evaluate the accuracy of the labeled products, FDA does not specify acceptable sources for the labeled values.

Products with Separately Packaged Ingredients/Assortments of Foods/Gift Packages (21 CFR 101.9(h))

P1. Can the Nutrition Facts label on a box containing dry noodles and a seasoning packet list the nutrients in the noodles separately from the seasoning packet? If so, must a column be included that gives the total nutrients for the noodles and the seasoning packet?

Answer: Section 101.9(h)(1) provides the option of listing nutrition information per serving for each component or as a composite value. The decision is up to the manufacturer. A column of total values is not required.

P2. What are the labeling options for products packed in an assortment that are intended to be eaten at the same time? Can the nutrient analysis for a product containing a mixture of nuts or different types of dried fruit be based on a composite of the mixture blended together?

Answer: Section 101.9(h)(1) of the final regulations pertaining to nutrition labeling of foods allows the nutrition information for assortments of the same type of food (e.g., mixed nuts or mixed fruits) that are intended to be consumed at the same time to be specified for each component or as a composite value. Therefore, if it is reasonable to assume that a consumer would eat an assortment of the nuts or fruits offered, a single composite analysis may be used to determine the nutrient composition.

P3. What is the correct way to label a gift basket that contains a variety of foods, candies, and liquors of various sizes? Does nutrition labeling have to be provided for each individually wrapped product, and are such packages considered multi-packs?

Answer: Nutrition labeling of gift food packages is addressed in 21 CFR 101.9(h)(3) which:

1. allows nutrition information to be placed on labeling inside the package,
2. provides for standardized serving sizes when there is no RACC appropriate for the variety of foods in the gift pack,
3. allows number of servings per container to be listed as "varied,"
4. allows nutrition information to be given as a composite for categories of foods in the gift pack that have similar dietary uses and similar nutritional

characteristics (e.g., assorted chocolate candies, assorted cheeses), and
5. does not require declaration of nutrients in free promotional items or items used in small quantities to enhance the appearance of the gift package.

The required nutrition information for different foods may be put on a brochure or package insert using the aggregate display illustrated in 21 CFR 101.9(d)(13)(ii). Listing the servings per container as "varied" allows use of the same nutrition label on packages of varied sizes.

If some individually wrapped food items in the gift pack bear nutrition labeling, that information need not be repeated with the nutrition information provided for the unlabeled foods (e.g., on the outside of the gift pack or on a package insert). Further, the labeling of all malt beverages, regardless of alcohol content, and of liquors and wines containing 7 percent or more by volume of alcohol is regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB). TTB does not require that the products it regulates bear nutrition labeling.

P4. A retailer assembles gift packages containing a mixture of prepackaged and pre-labeled foods from the following categories: (1) Food items in packages that bear Nutrition Facts in accordance with 21 CFR 101.9, (2) packages with less than 12 square inches of available label space that contain a phone number where nutrition information may be obtained. What are the nutrition labeling requirements for gift packages containing these foods?

Answer: Gift packages are required to bear nutrition labeling in accordance with current labeling regulations. The following rules apply to the above categories:

1. When individual food packages within a gift package bear complete nutrition labeling, the nutrition information need not be repeated on the outer wrapper or in a package insert, even when such means are used to convey nutrition information on other products within the gift package.
2. Available label space is not an issue for most gift packages since the required information may be placed on the larger outer wrapper or in a package insert. Therefore, when packages with less than 12 square inches of available label space are added to a gift package, the nutrition information should be obtained from the manufacturer and placed on or within the gift package. Free promotional items and items used in small quantities to enhance the appearance of the gift package are excused from this requirement (21 CFR 101.9(h)(3)(v)).
3. Nutrition labeling must be placed on the outer wrapper or on a package insert for all foods in a gift package (except free promotional items and items used in small quantities to enhance the appearance of the gift package) that do not bear the required nutrition information on the package label.

P5. Must inserts for gift packages follow the standard format? May other displays such as the tabular display be used on the insert?

Answer: The full format must be used because the space available is not limited by the size of the label.

P6. Is nutrition labeling required for fresh fruit included in a gift package?

Answer: Nutrition labeling is not required when the entire package is made up of fresh fruits (which fall under the voluntary nutrition labeling program) or when the fruit is packed with other processed foods that are intended to be eaten separately. However, if the fruit is included as one part of a kit with more than one ingredient, and some of the other ingredients are not subject to the voluntary labeling exemption, nutrition labeling is required (e.g., apples and caramel sauce).

P7. When cello pack labeling of fresh fruits or vegetables includes a claim, must nutrition information be provided on the label?

Answer: Claims subject the food to nutrition labeling in accordance with 21 CFR 101.45, which means that nutrition information will have to be available at point of purchase although not necessarily on the package.

P8. I assemble gift packs using prepackaged foods manufactured by other companies. Labeling on my part is limited to adding a "Contents List" which includes my company name and address. The gift pack is featured in the same manner in my catalogue. While some of these products have nutrition labeling, some do not because the manufacturers have a small business exemption and no claims are made. Am I responsible for providing nutrition labeling for the items that do not carry nutrition information?

Answer: Nutrition labeling must be made available for all foods in a gift pack unless the packer, as well as the manufacturer, qualifies for a small business exemption. Section 101.9(h)(3)(i) allows for the added nutrition information to be placed on an insert in the gift pack rather than on each package label.

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IX. Appendix A: Definitions of Nutrient Content Claims

Content Claims
("Free," "Low," "Reduced/Less")

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

Definitions of Nutrient Content Claims

Nutrient	Free	Low	Reduced/Less	Comments
Calories 21 CFR 101.60(b)	Less than 5 cal per RACC and per labeled serving	40 cal or less per RACC (and per 50 g if RACC is small) Meals and main dishes: 120 cal or	At least 25% fewer calories per RACC than an appropriate reference food (or for meals and main dishes, at least	"Light" or "Lite": if 50% or more of the calories are from fat, fat must be reduced by at least 50% per RACC. If less than 50% of calories are from fat, fat must be reduced at least 50% or calories reduced at least 1/3 per RACC

		less per 100 g	25% fewer calories per 100g) Reference food may not be "Low Calorie" Uses term "Fewer" rather than "Less"	"Light" or "Lite" meal or main dish product meets definition for "Low Calorie" or "Low Fat" meal and is labeled to indicate which definition is met For dietary supplements: Calorie claims can only be made when the reference product is greater than 40 calories per serving
Total Fat 21 CFR 101.62(b)	Less than 0.5 g per RACC and per labeled serving (or for meals and main dishes, less than 0.5 g per labeled serving) Contains no ingredient that is fat or understood to contain fat, except noted below (*).	3 g or less per RACC (and per 50 g if RACC is small) Meals and main dishes: 3 g or less per 100 g and not more than 30% of calories from fat	At least 25% less fat per RACC than an appropriate reference food (or for meals and main dishes, at least 25% less fat per 100g) Reference food may not be "Low Fat"	"__% Fat Free": may be used if food meets the requirements for "Low Fat" 100% Fat Free: food must be "Fat Free" "Light"--see previous Calorie comments For dietary supplements: total fat claims cannot be made for products that are 40 calories or less per serving
Saturated Fat 21 CFR 101.62(c)	Less than 0.5 g saturated fat and less than 0.5 g *trans* fatty acids per RACC and per labeled serving (or for meals and main dishes, less than 0.5 g saturated fat and less than 0.5 g *trans* fatty acids per labeled serving) Contains no ingredient that is understood to contain saturated fat except as noted below (*)	1 g or less per RACC and 15% or less of calories from saturated fat Meals and main dishes: 1 g or less per 100 g and less than 10% of calories from saturated fat	At least 25% less saturated fat per RACC than an appropriate reference food (or for meals and main dishes, at least 25% less saturated fat per 100g) Reference food may not be "Low Saturated Fat"	Next to all saturated fat claims, must declare the amount of cholesterol if 2 mg or more per RACC; and the amount of total fat if more than 3 g per RACC (or 0.5 g or more of total fat per RACC for "Saturated Fat Free") (or for meals and main dishes, per labeled serving) For dietary supplements: saturated fat claims cannot be made for products that are 40 calories or less per serving

Cholesterol 21 CFR 101.62(d)	Less than 2 mg per RACC and per labeled serving (or for meals and main dishes, less than 2 mg per labeled serving) Contains no ingredient that contains cholesterol except as noted below (*)	20 mg or less per RACC (and per 50 g of food if RACC is small) Meals and main dishes: 20 mg or less per 100 g	At least 25% less cholesterol per RACC than an appropriate reference food (or for meals and main dishes, at least 25% less cholesterol per 100g) Reference food may not be "Low Cholesterol"	Cholesterol claims only allowed when food contains 2 g or less saturated fat per RACC; or for meals and main dish products, per labeled serving size for "Free" claims or per 100 g for "Low" and "Reduced/Less" claims Must declare the amount of total fat next to cholesterol claim when fat exceeds 13 g per RACC and labeled serving (or per 50 g of food if RACC is small), or when the fat exceeds 19.5 g per labeled serving for main dishes or 26 g for meal products For dietary supplements: cholesterol claims cannot be made for products that are 40 calories or less per serving
Sodium 21 CFR 101.61	Less than 5 mg per RACC and per labeled serving (or for meals and main dishes, less than 5 mg per labeled serving Contains no ingredient that is sodium chloride or generally understood to contain sodium except as noted below (*) "Salt Free" must meet criterion for "Sodium Free"	140 mg or less per RACC (and per 50 g if RACC is small) Meals and main dishes: 140 mg or less per 100g "Very Low Sodium": 35 mg or less per RACC (and per 50g if RACC is small). For meals and main dishes: 35mg or less	At least 25% less sodium per RACC than an appropriate reference food (or for meals and main dishes, at least 25% less sodium per 100g) Reference food may not be "Low Sodium"	"Light" (for sodium reduced products): if food is "Low Calorie" and "Low Fat" and sodium is reduced by at least 50% "Light in Sodium": if sodium is reduced by at least 50% per RACC. For meals and main dishes, "Light in Sodium" meets definition for "Low in Sodium" "No Salt Added" and "Unsalted" must declare "This is Not A Sodium Free Food" on information panel if food is not "Sodium Free" "Lightly Salted": 50% less

		per 100g		sodium than normally added to reference food and if not "Low Sodium", so labeled on information panel
Sugars 21 CFR 101.60(c)	"Sugar Free": Less than 0.5 g sugars per RACC and per labeled serving (or for meals and main dishes, less than 0.5 g per labeled serving) Contains no ingredient that is a sugar or generally understood to contain sugars except as noted below (*) Disclose calorie profile (e.g., "Low Calorie")	Not Defined.	At least 25% less sugars per RACC than an appropriate reference food (or for meals and main dishes, at least 25% less sugar per 100g) May not use this claim on dietary supplements of vitamins and minerals	"No Added Sugars" and "Without Added Sugars" are allowed if no sugar or sugar containing ingredient is added during processing. State if food is not "Low" or "Reduced Calorie" The terms "Unsweetened" and "No Added Sweeteners" remain as factual statements Does not include sugar alcohols

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

- RACC = Reference Amounts Customarily Consumed.
- Small RACC = Reference Amounts Customarily Consumed 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 RACC, the per 50 g criterion refers to the prepared form of the food).
- When levels exceed: 13 g Total Fat, 4 g Saturated Fat, 60 mg Cholesterol, and 480 mg Sodium per RACC, per labeled serving or, for foods with small RACC, 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).

CFSAN/Office of Nutrition, Labeling, and Dietary Supplements
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X. Appendix B: Additional Requirements for Nutrient Content Claims

Contains Nonbinding Recommendations

Relative Claims

To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified below (21 CFR 101.13(j)(1)):

"Light"	(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)

"Reduced" and "Added" (or "Extra," "Plus," "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.

For all relative claims, the percent (or fraction) of change and identity of reference food must be declared immediately adjacent to the most prominent claim. 21 CFR 101.13(j)(2)(i) and 21 CFR 101.13(j)(2)(ii)

Other Nutrient Content Claims

Quantitative comparison of the amount of the nutrient in the product per labeled serving with that in the reference food must be declared on information panel. 21 CFR 101.13(j)(2)(iv)(A)

A relative claim for decreased levels of a nutrient may not be made if the nutrient content of the reference food meets the requirement for a "low" claim for that nutrient (e.g., 3 g fat or less). 21 CFR 101.13(j)(3)

Claim	**Requirements**
"High," "Rich In," or "Excellent Source Of"	Contains 20% or more of the DV per RACC. May be used on meals or main dishes to indicate that the product contains a food that meets the definition.
"Good Source," "Contains," or "Provides"	10%-19% of the DV per RACC. These terms may be used on meals or main dishes to indicate that the product contains a food that meets the definition.
"More," "Fortified," "Enriched," "Added," "Extra," or "Plus"	10% or more of the DV per RACC. May only be used for vitamins, minerals, protein, dietary fiber, and potassium.
"Lean"	On seafood or game meat products that contain less than 10g total fat, 4.5g or less saturated fat, and less than 95mg cholesterol per RACC and per 100g (for meals & main dishes, meets criteria per 100g and per labeled serving). On mixed dishes not measurable with a cup (as defined in 21 CFR 101.12(b) in table 2) that contain less than 8g total fat, 3.5g or less saturated fat and less than 80 mg cholesterol per RACC.

"Extra Lean"	On seafood or game meat products that contains less than 5g total fat, less than 2g saturated fat and less than 95mg cholesterol per RACC 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 RACC 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 RDIs and that are present in the product at 2% or more of the RDI (e.g., "High potency multivitamin, multimineral dietary supplement tablets").
"Modified"	May be used in statement of identity of a food that bears a relative claim (e.g., "Modified fat cheesecake, contains 35% less fat than our regular cheesecake.")
"Fiber" Claims	If a fiber claim is made and the food is not low in total fat, then the label must disclose the level of total fat per labeled serving. 21 CFR 101.54(d)(1)
Claims using the term "antioxidant"	For claims characterizing the level of antioxidant nutrients in a food: 1. an RDI must be established for each of the nutrients that are the subject of the claim; 2. each nutrient must have existing scientific evidence of antioxidant activity; 3. the level of each nutrient must be sufficient to meet the definition for "high," "good source," or "more"; 4. 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.

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.
- 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.
- The term "healthy" and related terms ("health," "healthful," "healthfully," "healthfulness,"

"healthier," "healthiest," "healthily" and "healthiness") may be used if the food meets the following requirements:

Conditions for the Use of "Healthy"

Individual Food	Seafood/Game Meat	Meal/Main Dish
low fat	**TOTAL FAT** < 5 g fat /RACC & /100g	low fat
low sat fat	**SATURATED FAT** < 2 g sat fat /RACC & /100g	low sat fat
≤ 480 mg /RACC and /l.s.; or /50 g, if RACC is small	**SODIUM** ≤ 480 mg /RACC and /l.s.; or /50 g, if RACC is small	≤ 600 mg /l.s.
≤ disclosure level	**CHOLESTEROL** < 95 mg /RA & /100 g	≤ 90 mg /l.s.
Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber except: raw fruits and vegs.; frozen or canned single ingredient fruits and vegs. (may include ingredients whose addition does not change the nutrient profile of the fruit or veg.); enriched cereal-grain products that conform to a standard of identity in 21 CFR 136, 137, or 139.	**BENEFICIAL NUTRIENTS** Contains at least 10% of DV /RACC for vitamins A, C, calcium, iron, protein, or fiber	Contains at least 10% of the DV /l.s. of two nutrients (for a main dish product) or of three nutrients (for a meal product) of vit. A, vit. C, calcium, iron, protein, or fiber.
Per 21 CFR 104.20	**FORTIFICATION** Per 21 CFR 104.20	Per 21 CFR 104.20
NOTE: l.s. = labeled serving; RACC = Reference Amount Customarily Consumed per Eating Occasion; small RACC = 30 g or less, or 2 tablespoons or less		

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.

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XI. Appendix C: Health Claims

Requirements for Health Claims Made in Labeling

Approved Claims	Requirements for the Food	Claim Requirements	Model Claim, Statements
Calcium and Osteoporosis (21 CFR 101.72)	- High in calcium, - Assimilable (Bioavailable), - Supplements must disintegrate and dissolve, and - Phosphorus content cannot exceed calcium	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.	Regular exercise and a healthy diet with enough calcium helps teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

	content	Additional factors necessary to reduce risk: Eating healthful meals, regular exercise. Mechanism relating calcium to osteoporosis: Optimizes peak bone mass. Foods or supplements containing more than 400 mg calcium must state that total intakes of greater than 2,000 mg calcium provide no added benefit to bone health.	
Sodium and Hypertension (21 CFR 101.74)	- Low sodium	*Required terms*: - "Sodium", "High blood pressure" Includes physician statement (Individuals with high blood pressure should consult their physicians) if claim defines high or normal blood pressure	Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.
Dietary Fat and Cancer (21 CFR 101.73)	- Low fat (Fish & game meats: "Extra lean")	*Required terms*: - "Total fat" or "Fat" - "Some types of cancers" or "Some cancers" Does not specify types of fats or fatty acids that may be related to risk of cancer.	Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.
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	While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.

		should consult their physicians) if claim defines high or normal blood total--and LDL--cholesterol.	
Fiber-Containing Grain Products, Fruits, and Vegetables and Cancer (21 CFR 101.76)	- A grain product, fruit, or vegetable that contains dietary fiber; - Low fat, and - Good source of dietary fiber (without fortification)	*Required terms*: - "Fiber", "Dietary fiber", or "Total dietary fiber" - "Some types of cancer" or "Some cancers" Does not specify types of dietary fiber that may be related to risk of cancer.	Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.
Fruits, Vegetables and Grain Products that contain Fiber, particularly Soluble Fiber, and Risk of Coronary Heart Disease (21 CFR 101.77)	- A fruit, vegetable, or grain product that contains fiber; - Low saturated fat, - Low cholesterol, - Low fat, - At least 0.6 grams of soluble fiber per RACC (without fortification), and, - Soluble fiber content provided on label	*Required terms*: - "Fiber", "Dietary fiber", "Some types of dietary fiber", "Some dietary fibers", or "Some fibers" - "Saturated fat" and "Cholesterol" - "Heart disease" or "Coronary heart disease" Includes physician statement ("Individuals with elevated blood total--or LDL--cholesterol should consult their physicians") if claim defines high or normal blood total--and LDL--cholesterol.	Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.
Fruits and Vegetables and Cancer (21 CFR 101.78)	- A fruit or vegetable, - Low fat, and - Good source (without fortification) of at	*Required terms*: - "Fiber", "Dietary fiber", or "Total dietary fiber"; - "Total fat" or "Fat", - "Some types of cancer" or	Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, Vitamin A, or Vitamin C) may reduce the risk of some types of cancer, a disease associated with

	least one of the following • Vitamin A, • Vitamin C, or • Dietary fiber	"Some cancers" Characterizes fruits and vegetables as "Foods that are low in fat and may contain Vitamin A, Vitamin C, and dietary fiber." Characterizes specific food as a "Good source" of one or more of the following: Dietary fiber, Vitamin A, or Vitamin C. Does not specify types of fats or fatty acids or types of dietary fiber that may be related to risk of cancer.	disease associated with many factors. Broccoli is high in vitamin A and C, and it is a good source of ditary fiber.
Folate and Neural Tube Defects (21 CFR 101.79)	"Good source" of folate (at least 40 mcg folate per serving) Dietary supplements, or foods in conventional food form that are naturally good sources of folate (i.e., only non-fortified food in conventional food 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	*Required terms*: - Terms that specify the relationship (e.g., women who are capable of becoming pregnant and who consume adequate amounts of folate) "Folate", "folic acid", "folacin","folate a B vitamin", "folic acid, a B vitamin," "folacin, a 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.	Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord defect.

	meet USP standards for disintegration and dissolution or otherwise bioavailable Amount of folate required in Nutrition Label		
Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries (21 CFR 101.80)	- Sugar free, and - When a fermentable carbohydrate is present, the food must not lower plaque pH below 5.7. **Eligible substances** 1) The following sugar alcohols: xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these. 2) The following sugar: D-tagatose 3) The following non-nutritive sweetener:	*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; -"dental caries" or "tooth decay." -"sugar alcohol" or "sugar alcohols" or the name or names of the sugar alcohols; or D-tagatose, or sucralose Note: D-tagatose may be identified as "tagatose" When the substance that is the subject of the claim is a noncariogenic sugar (i.e., D-tagatose) the claim shall identify the substance as a sugar that, unlike other sugars, does not promote the development of dental caries. Includes statement that frequent between meal consumption of foods high in sugars and starches can promote tooth decay. Packages with less than 15 square inches of surface area available for labeling may use a	**Full claim**: Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay. **Shortened claim(on small packages only)**: Does not promote tooth decay.

	sucralose	shortened claim.	
Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease (21 CFR 101.81)	- Low saturated fat - Low cholesterol - Low fat, and - The food product must include one or more of the following whole oat or barley foods: 1) oat bran, 2) rolled oats, 3) whole oat flour, 4) whole grain barley or dry milled barley, and the whole oat or barley foods must contain at least 0.75 g of soluble fiber per RACC of the food product; *or* Oatrim that contains at least 0.75 g of beta-glucan soluble per RACC of the food product; *or* Psyllium husk that contains at least 1.7 g of soluble fiber per RACC of food product. **Eligible Sources of Soluble Fiber** Beta-glucan soluble fiber from the following whole oat and barley sources: 1) Oat bran	*Required terms*: - "Heart disease" or "coronary heart disease." - "Saturated fat" and "cholesterol." In specifying the substance the claim uses the term "soluble fiber" qualified by the name of the eligible source of the soluble fiber, which is either whole oat or barley or psyllium seed husk. Claim specifies the daily dietary intake of the soluble fiber source necessary to reduce the risk of CHD Claim specifies the amount of soluble fiber in one serving of the product. **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))	Soluble fiber from foods such as [*name of soluble fiber source, and, if desired, name of food product*], as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food product*] supplies __ grams of the [necessary daily dietary intake for the benefit] soluble fiber from [*name of soluble fiber source*] necessary per day to have this effect.

	2) Rolled Oats 3) Whole Oat Flour 4) Oatrim 5) Whole Grain Barley and Dry Milled Barley 6) Soluble fiber from psyllium husk with purity of no less than 95% The amount of soluble fiber per RACC must be declared in nutrition label.		
Soy Protein and Risk of Coronary Heart Disease (21 CFR 101.82)	- At least 6.25 g soy protein per RACC - 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 grams of soy protein a day, as part of a low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [*name of food*] supplies __ grams of soy protein. (2) Diets low in saturated fat and cholesterol that include 25 grams of soy protein a day may reduce the risk of heart disease. One serving of [*name of food*] provides __ grams of soy protein.
Plant Sterol/stanol esters and Risk of	- At least 0.65 g plant sterol esters per RACC of spreads and salad	*Required terms*: - "May" or "might" reduce the risk of CHD	(1) Foods containing at least 0.65 gram per of vegetable oil sterol esters, eaten twice a day with

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

FDAMA (FDA Modernization Act) Health Claims (Health Claims Authorized Based on an Authoritative Statement by Federal Scientific Bodies)

Approved Claims	Food Requirements	Claim Requirements	Model Claim Statements
Whole Grain Foods and Risk of Heart Disease and Certain Cancers	Contains 51 percent or more whole grain ingredients by weight per RACC, and - Dietary fiber content at least:	*Required wording of the claim*: "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and	NA

(Docket No. 1999P-2209)	• 3.0 g per RACC of 55 g • 2.8 g per RACC of 50 g • 2.5 g per RACC of 45 g • 1.7 g per RACC of 35 g - Low fat	cholesterol may reduce the risk of heart disease and some cancers."	
Potassium and the Risk of High Blood Pressure and Stroke (Docket No. 2000Q-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
Fluoridated Water and Reduced Risk of Dental Carries (Docket No. 2006Q-0418)	- Bottled water meeting the standards of identity and quality set forth in 21 CFR 165.110 - Meet all general requirements for health claims in 21 CFR 101.14) with the exception of the minimum nutrient contribution (21 CFR 101.14(e)(6)), - Total Fluoride >0.6 to 1.0 mg/L - Excluding bottled water products specifically marketed for use by infants	*Required wording for the claim*: "Drinking fluoridated water may reduce the risk of [dental caries or tooth decay]".	NA
Saturated Fat, Cholesterol, and *Trans* Fat, and Reduced Risk of Heart Disease (Docket No. 2006Q-0458)	-Low saturated fat -Low cholesterol -Bear quantitative *trans* fat labeling -Contain less than 0.5 g *trans* fat per RACC	*Required wording for the claim*: "Diets low in saturated fat and cholesterol, and as low as possible in *trans* fat, may reduce the risk of heart disease."	NA

	-Contain less than 6.5 g total fat		

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XII. Appendix D: Qualified Health Claims

Contains Nonbinding Recommendations

FDA will exercise enforcement discretion for qualified health claims when the claim meets all general

requirements of 21 CFR 101.14, *except* for the requirements that the claim meet the significant scientific agreement standard and that the claim be made in accordance with an authorizing regulation. Other factors that FDA will consider in exercising enforcement discretion are listed in the following qualified health claim table.

Qualified Health Claims	Eligible Foods	Factors for Exercising Enforcement Discretion	Claim Statements
0.8 mg Folic Acid & Neural Tube Birth Defects Docket No. 1991N-100H 10/10/2000 enforcement discretion letter 04/03/2001 clarification letter ***Note:*** *there also is a folic acid/neural tube defect health claim authorized by regulation (see 21 CFR 101.79).*	Dietary supplements containing folic acid	The disclaimer (i.e., FDA does not endorse this claim...) is placed immediately adjacent to and directly beneath the claim (i.e., 0.8 mg folic acid ...), with no intervening material, in the same size, typeface, and contrast as the claim.	0.8 mg folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form. FDA does not endorse this claim. Public health authorities recommend that women consume 0.4 mg folic acid daily from fortified foods or dietary supplements or both to reduce the risk of neural tube defects.
B Vitamins & Vascular Disease Docket No. 1999P-3029 11/28/2000 enforcement discretion letter 05/15/2001 clarification letter	Dietary supplements containing vitamin B6, B12, and/or folic acid	The disclaimer (i.e., FDA evaluated the above claim...) must be immediately adjacent to and directly beneath the first claim (i.e., As part of a well-balanced diet...) with no intervening material that separates the claim from the disclaimer, and the second sentence must be in the same size, type face and contrast as the first sentence. Products that contain more than 100 percent of the Daily Value (DV) of folic acid (400 micrograms), when labeled for	As part of a well-balanced diet that is low in saturated fat and cholesterol, Folic Acid, Vitamin B6 and Vitamin B12 may reduce the risk of vascular disease. FDA evaluated the above claim and found that, while it is known that diets low in saturated fat and cholesterol reduce the risk of heart disease and

		use by adults and children 4 or more years of age, must identify the safe upper limit of daily intake with respect to the DV. The folic acid safe upper limit of daily intake value of 1,000 micrograms (1 mg) may be included in parentheses. The claim does not suggest a level of vitamins B6, B12, and/or folic acid as being useful in achieving the claimed effect. Dietary supplements containing folic acid must meet the United States Pharmacopeia (USP) standards for disintegration and dissolution, except that if there are no applicable USP standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.	other vascular diseases, the evidence in support of the above claim is inconclusive.
Selenium & Cancer Docket No. 2002P-0457 02/21/2003 enforcement discretion letter 04/28/2003 clarification letter	Dietary supplements containing selenium	The disclaimer (i.e., Some scientific evidence suggests...) is placed immediately adjacent to and directly beneath the claim (i.e., Selenium may reduce the risk), with no intervening material, in the same size, typeface, and contrast as the claim itself The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Level established by the National Academy of Sciences/Institute of Medicine for selenium (400 micrograms per day).	(1) Selenium may reduce the risk of certain cancers. Some scientific evidence suggests that consumption of selenium may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive. *or,* (2) Selenium may produce anticarcinogenic effects in the body. Some scientific

		Paragraph 101.14(d)(2)(vii) requires that the dietary supplement bearing the claim meet the nutrient content claim definition for high (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for selenium is 14 micrograms.	evidence suggests that consumption of selenium may produce anticarcinogenic effects in the body. However, FDA has determined that this evidence is limited and not conclusive.
Antioxidant Vitamins & Cancer Docket No. 1991N-0101 04/01/2003 enforcement discretion letter	Dietary supplements containing vitamin E and/or vitamin C	The disclaimer (i.e., ...evidence is limited and not conclusive) is placed immediately adjacent to and below the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. The supplement does not recommend or suggest in its labeling, or under ordinary conditions of use, a daily intake exceeding the Tolerable Upper Intake Levels established by the Institute of Medicine for vitamin C (2000 mg per day) or for vitamin E (1000 mg per day). Paragraph 101.14(d)(2)(vii) requires that the food bearing the claim meet the nutrient content claim definition for *high* (i.e., 20% or more of the daily value (DV) per RACC). 20% DV for vitamin C is 12 mg; 20% DV for vitamin E is 6 IU.	(1) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA has determined that this evidence is limited and not conclusive. *or,* (2) Some scientific evidence suggests that consumption of antioxidant vitamins may reduce the risk of certain forms of cancer. However, FDA does not endorse this claim because this evidence is limited and not conclusive. *or,* (3) FDA has determined that although some scientific evidence suggests that consumption of

			antioxidant vitamins may reduce the risk of certain forms of cancer, this evidence is limited and not conclusive.
Phosphatidylserine & Cognitive Dysfunction and Dementia Docket No. 2002P-0413 02/24/2003 enforcement discretion letter 05/13/2003 clarification letter 11/24/2004 updated letter	Dietary supplements containing soy-derived phosphatidylserine	The disclaimer (i.e., Very limited and preliminary scientific research...) is placed immediately adjacent to and directly beneath the claim (i.e., Phosphatidylserine may reduce...), with no intervening material, in the same size, typeface, and contrast as the claim itself. The claim does not suggest a level of phosphatidylserine as being useful in achieving the claimed effect. The soy-derived phosphatidylserine used is of very high purity.	(1) Consumption of phosphatidylserine may reduce the risk of dementia in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of dementia in the elderly. FDA concludes that there is little scientific evidence supporting this claim. *or,* (2) Consumption of phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. Very limited and preliminary scientific research suggests that phosphatidylserine may reduce the risk of cognitive dysfunction in the elderly. FDA concludes that there is little scientific evidence

			supporting this claim.
Nuts & Heart Disease Docket No. 2002P-0505 07/14/2003 enforcement discretion letter	(1) *Whole or chopped nuts* listed below that are raw, blanched, roasted, salted, and/or lightly coated and/or flavored; any fat or carbohydrate added in the coating or flavoring must meet the 21 CFR 101.9(f)(1) definition of an insignificant amount. (2) *Nut-containing products* other than whole or chopped nuts that contain at least 11 g of one or more of the nuts listed below per RACC. (3) Types of nuts eligible for this claim are restricted to almonds, hazelnuts, peanuts, pecans, some pine nuts, pistachio nuts, and walnuts. Types of nuts on which the health claim may be based is restricted to those nuts that were specifically included in the health claim petition, but that do not exceed 4 g saturated fat per 50 g of nuts.	***Whole or chopped nuts*** Whole or chopped nuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). Only walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber. Where the claim is used on whole or chopped nuts, the disclosure statement (see nutrition information...) must be placed immediately adjacent to and directly beneath the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. Nuts bearing the claim must comply with the 21 CFR 101.14(a)(4) saturated fat disqualifying level (4 g saturated fat per 50 g nuts). ***Nut-containing products*** Nut-containing products bearing the claim must comply with all the 21 CFR 101.14(a)(4) disqualifying levels which are 13 g total fat, 4 g saturated fat, 60 mg of cholesterol, and 480 mg of sodium per RACC. The claim applies only to types of nuts that do not exceed the 21	Scientific evidence suggests but does not prove that eating 1.5 ounces per day of most nuts [such as *name of specific nut*] as part of a diet low in saturated fat and cholesterol may reduce the risk of heart disease. [See nutrition information for fat content.] *Note: The bracketed phrase naming a specific nut is optional. The bracketed fat content disclosure statement is applicable to a claim made for whole or chopped nuts, but not a claim made for nut-containing products.*

		CFR 101.14(a)(4) disqualifying nutrient level for saturated fat (4 g saturated fat per 50 g nuts). Nut-containing products bearing the claim must comply with the 21 CFR 101.62(c)(2) definition of a *low saturated fat food* and the 21 CFR 101.62(d)(2) definition of a *low cholesterol food*. Nut-containing products bearing the claim must comply with the 21 CFR 101.14(e)(6) requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber prior to any nutrient addition.	
Walnuts & Heart Disease Docket No. 2002P-029 03/09/2004 enforcement discretion letter	Whole or chopped walnuts	Walnuts do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). Walnuts do not need to comply with the requirement in § 101.14(e)(6) that the food contain a minimum of 10 percent of the Daily Value per RACC of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber. The disclosure statement about total fat content (i.e., See nutrition information for fat content) is placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.	Supportive but not conclusive research shows that eating 1.5 ounces per day of walnuts, as part of a low saturated fat and low cholesterol diet and not resulting in increased caloric intake, may reduce the risk of coronary heart disease. See nutrition information for fat [and calorie] content. *Notes: The bracketed phrase "and calorie" is optional in that*

			FDA does not intend for the presence or absence of such phrase to be a factor in whether it considers enforcement discretion for the use of the qualified health claim. FDA considered this additional information beneficial to consumers to heighten their awareness of the caloric contribution from walnuts and encourages companies to include it in product labeling.
Omega-3 Fatty Acids & Coronary Heart Disease Docket No. 2003Q-0401 09/08/2004 enforcement discretion letter - Wellness Petition 09/08/2004 enforcement discretion letter - Martek Petition	Conventional foods and dietary supplements that contain EPA and DHA omega-3 fatty acids.	Dietary supplements should not recommend or suggest in their labeling a daily intake exceeding 2 grams of EPA and DHA **Total fat content** Dietary supplements that weigh 5 g or less per RACC (RACC for dietary supplement is labeled serving size) are exempted from the total fat disqualifying level, but if dietary supplements that weigh 5 g or less per RACC exceed the total fat disqualifying level (13.0 g per 50 g) the disclosure statement (i.e., "See nutrition information for total fat content") must be placed immediately adjacent to the health claim. Dietary	Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]

		supplements that weigh more than 5 g per RACC must not exceed the total fat disqualifying level (13.0 g per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp). (See "Qualified Health Claims Subject to Enforcement Discretion, Omega-3 Fatty Acids and Coronary Heart Disease" and the enforcement discretion letter for Omega-3 Fatty Acids and Coronary Heart Disease) Fish (i.e., "products that are essentially all fish") may not exceed 16.0 g total fat per RACC. Fish with a total fat content greater than 13.0 g per RACC must include "See nutrition information for total fat content" with the health claim. The "products that are essentially all fish" include fish without any added ingredients and fish with a small amount of added fat or carbohydrate that meets the definition of an insignificant amount in 21 CFR 101.9(f)(1). Examples of these products are raw fish, boiled fish, and broiled fish. **Conventional foods** other than fish may not exceed the total fat disqualifying levels. For individual foods, the total fat disqualifying level is 13.0 g per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp. The total fat disqualifying level is 26.0 g per label serving size for meal products and 19.5 g per label serving size for main dish products. **Saturated fat content**	*Note: Dietary supplements may declare the amount of EPA and DHA per serving in "Supplement Facts," instead of making the declaration in the claim.*

Dietary supplements must meet the criterion for low saturated fat with regard to the saturated fat content (≤ 1 g per RACC) but not with regard to the no more than 15 percent calories from saturated fat criterion.

Fish may not exceed the saturated fat disqualifying level of 4.0 g per RACC (or 4.0 g per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp).

Conventional foods other than fish must meet the criteria for low saturated fat (≤ 1 g per RACC and no more than 15 percent of calories from saturated fat for individual foods, ≤ 1 g per 100 g and less than 10 percent calories from saturated fat for meal products and main dish products). There is an error in the enforcement discretion letters in the section of "low saturated fat," stating that meal products and main dishes meet all criteria specified for the "low saturated fat" criteria (21 CFR 101.62(c)(2)). The CFR number should be (21 CFR 101.62(c)(3)).

Cholesterol content

Dietary supplements that weigh 5 g or less per RACC are exempt from the cholesterol disqualifying level (60 mg per 50 g), but those that exceed the cholesterol disqualifying level must include "See nutrition information for cholesterol content" with the qualified health claim. Dietary supplements that weigh more than 5 g per RACC must meet

the criterion for low cholesterol (≤ 20 mg per 50g).

Fish must meet the extra lean criterion with regard to cholesterol content (< 95 mg per RACC and per 100 g, whichever is greatest), but not with regard to saturated fat content. Fish with cholesterol content greater than 60 mg per RACC must include "See nutrition information for cholesterol content" with the qualified health claim.

Conventional foods other than fish must meet the low cholesterol criterion (21 CFR 101.62(d)(2)). See 21 CFR 101.62(d)(2) for the low cholesterol criterion specific for individual foods, meal products, and main dish products.

Sodium

All conventional foods and dietary supplements must meet the sodium disqualifying level (≤ 480 mg per RACC and per 50 g if RACC is ≤ 30 g or ≤ 2 tbsp for individual foods, ≤ 960 mg per label serving size for meal products, ≤ 720 mg per label serving size for main dish products).

The 10 percent minimum nutrient requirement

All conventional foods must meet the 10 percent minimum nutrient requirement (Vitamin A 500 IU, Vitamin C 6 mg, Iron 1.8 mg, Calcium 100 mg, Protein 5 g, Fiber 2.5 g per RACC), prior to any nutrient

		addition. The 10 percent minimum nutrient requirement does not apply to dietary supplements (21 CFR 101.14(e)(6)).	
Monounsaturated Fatty Acids From Olive Oil and Coronary Heart Disease Docket No. 2003Q-0559 11/01/2004 enforcement discretion letter	All products that are essentially pure olive oil and labeled as such (see * for definitions) Dressings for salads (i.e. salad dressings) that contain 6 g or more olive oil per Reference Amount Customarily Consumed (RACC), are low in cholesterol (21 CFR 101.62(d)(2)), and do not contain more than 4 g of saturated fat per 50 g. Vegetable oil spreads that contain 6 g or more olive oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)) and do not contain more than 4 g of saturated fat per RACC. Olive oil-containing foods that contain 6 g or more olive oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber. If the	Olive oil, vegetable oil spreads, dressings for salads, shortenings and olive-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). The requirement that the food comply with the 50 gram-criterion of the saturated fat disqualifying level (21 CFR 101.14(e)(3)) does not apply to olive oil, vegetable oil spreads, and shortenings. The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to olive oil, dressings for salads, and shortenings. When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or olive-oil containing foods the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. When the food does not meet	Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil. *Note: The last sentence of the claim "One serving of this product contains [x] grams of olive oil." is optional when the claim is used on the label or in the labeling of olive oil.* *(1) Olive oil means virgin olive

	RACC of the olive oil-containing food is greater than 30 g the food cannot contain more than 4 g of saturated fat per RACC and if the RACC of the olive oil-containing food is 30 g or less the food cannot contain more than 4 g of saturated fat per 50 g. Shortenings that contain 6 g or more olive oil per RACC and are low in cholesterol (21 CFR 101.62(d)(2)) and do not contain more than 4 g of saturated fat per RACC. Meal products (21 CFR 101.13(l)) or Main dish products (21 CFR 101.13(m)) are not eligible for the claim.	the definition of low saturated fat (21 CFR 101.62(c)(2)) the disclosure statement (i.e., See nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. If both of the above two conditions are met the disclosure statements for total fat and saturated fat can be combined (i.e., See nutrition information for total and saturated fat content).	oil, or blends of virgin olive oil and refined olive oil; where virgin olive oil is the oil resulting from the first pressing of olives and is suitable for human consumption without further processing and refined olive oil is the oil obtained from subsequent pressings and which is suitable for human consumption by refining processes which neutralize the acidity or remove particulate matter. (2) Vegetable oil spread means margarine (21 CFR 166.110) and margarine-like products. (3) "dressings for salads" means dressings for salads formulated to contain olive oil. (4) "shortenings" means vegetable oil shortenings, formulated to contain olive oil. (5) Olive oil-containing foods means foods, such

			as sauces or baked goods, excluding olive oil, vegetable oil spreads, dressings for salads, and shortenings.
Green Tea & Cancer Docket No. 2004Q-0083 06/30/2005 enforcement discretion letter	Green tea and conventional foods and dietary supplements that contain green tea	*Green tea* does not exceed the disqualifying nutrient levels for total fat, saturated fat, cholesterol, and sodium specified in 21 CFR 101.14(a)(4). FDA intends to consider the exercise of its enforcement discretion for qualified health claims for green tea and breast cancer and for green tea and prostate cancer to be used on the label or in the labeling of *green tea-containing foods* when the food does not exceed any of the disqualifying nutrient levels for fat, saturated fat, cholesterol, and sodium. FDA intends to consider the exercise of its enforcement discretion for *green tea* that does not meet the 10% minimum nutrient content requirement in 21 CFR 101.14(e)(6). FDA does not intend to consider the exercise of its enforcement discretion for *green tea-containing foods* that do not meet the requirements of 21 CFR 101.14(e)(6).	(1) Two studies do not show that drinking green tea reduces the risk of breast cancer in women, but one weaker, more limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of breast cancer. *or,* (2) One weak and limited study does not show that drinking green tea reduces the risk of prostate cancer, but another weak and limited study suggests that drinking green tea may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that green tea reduces the risk of prostate cancer.

Chromium Picolinate & Diabetes Docket No. 2004Q-0144 08/25/2005 enforcement discretion letter	Dietary supplements containing chromium	Dietary supplement containing chromium must meet or exceed the requirement for a "high" level of chromium as defined in 21 CFR 101.54(b) (i.e., 24 mg or more per RACC under the current regulation) for FDA to exercise enforcement discretion.	One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain.
Calcium and Colon/Rectal Cancer & Calcium and Recurrent Colon/Rectal Polyps Docket No. 2004Q-0097 10/12/2005 enforcement discretion letter	Dietary supplements containing calcium	The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in 21 CFR 101.54(b) (i.e., 200 mg or more calcium per RACC) The calcium content of the dietary supplement must be assimilable (i.e., bioavailable) (21 CFR 101.72(c)(ii)(B)), and meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts. For dietary supplements for which no U.S.P. standards exist, the dietary supplement must exhibit appropriate assimilability under the conditions of use stated on the product label (21 CFR 101.72(c)(ii)(C)).	**Colon/Rectal Cancer:** Some evidence suggests that calcium supplements may reduce the risk of colon/rectal cancer, however, FDA has determined that this evidence is limited and not conclusive. **Recurrent Colon Polyps:** Very limited and preliminary evidence suggests that calcium supplements may reduce the risk of colon/rectal polyps. FDA concludes that

			there is little scientific evidence to support this claim.
Calcium & Hypertension, Pregnancy-Induced Hypertension, and Preeclampsia Docket No. 2004Q-0098 10/12/2005 enforcement discretion letter	Dietary supplements containing calcium	The dietary supplement must meet or exceed the requirement for a "high" level of calcium as defined in 21 CFR 101.54(b) (i.e., 200 mg or more calcium per RACC) The calcium content of the dietary supplement must be assimilable (i.e., bioavailable) (21 CFR 101.72(c)(ii)(B)), and meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts. For dietary supplements for which no U.S.P. standards exist, the dietary supplement must exhibit appropriate assimilability under the conditions of use stated on the product label (21 CFR 101.72(c)(ii)(C)).	**Hypertension:** Some scientific evidence suggests that calcium supplements may reduce the risk of hypertension. However, FDA has determined that the evidence is inconsistent and not conclusive. **Pregnancy-Induced Hypertension:** Four studies, including a large clinical trial, do not show that calcium supplements reduce the risk of pregnancy-induced hypertension during pregnancy. However, three other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of pregnancy-induced

			hypertension. **Preeclampsia:** Three studies, including a large clinical trial, do not show that calcium supplements reduce the risk of preeclampsia during pregnancy. However, two other studies suggest that calcium supplements may reduce the risk. Based on these studies, FDA concludes that it is highly unlikely that calcium supplements reduce the risk of preeclampsia.
Tomatoes and/or Tomato Sauce & Prostate, Ovarian, Gastric, and Pancreatic Cancers Docket No. 2004Q-0201 11/08/2005 enforcement discretion letter - American Longevity Petition 11/08/2005 enforcement discretion letter -	(1) Cooked, Raw, Dried, or Canned Tomatoes (2) Tomato Sauces that contain at least 8.37 percent salt-free tomato solids		**Tomatoes and/or Tomato Sauce and Prostate Cancer:** Very limited and preliminary scientific research suggests that eating one-half to one cup of tomatoes and/or tomato sauce a week may reduce the risk of prostate cancer. FDA concludes that there is little scientific evidence

Lycopene Heath Claim Coalition Petition			supporting this claim. **Tomato Sauce and Ovarian Cancer:** One study suggests that consumption of tomato sauce two times per week may reduce the risk of ovarian cancer; while this same study shows that consumption of tomatoes or tomato juice had no effect on ovarian cancer risk. FDA concludes that it is highly uncertain that tomato sauce reduces the risk of ovarian cancer. **Tomatoes and Gastric Cancer:** Four studies did not show that tomato intake reduces the risk of gastric cancer, but three studies suggest that tomato intake may reduce this risk. Based on these studies, FDA concludes that it is unlikely that tomatoes reduce the risk of gastric cancer. **Tomatoes and**

			Pancreatic Cancer: One study suggests that consuming tomatoes does not reduce the risk of pancreatic cancer, but one weaker, more limited study suggests that consuming tomatoes may reduce this risk. Based on these studies, FDA concludes that it is highly unlikely that tomatoes reduce the risk of pancreatic cancer.
Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease Docket No. 2006Q-0091 10/06/2006 enforcement discretion letter	Canola oil (see * for definitions) Vegetable oil spreads, dressings for salads, shortenings, and canola oil-containing foods that contain 4.75 g or more of canola oil per RACC, are low in saturated fat (21 CFR 101.62(c)(2)), are low in cholesterol (21 CFR 101.62(d)(2)), and meet the saturated fat, cholesterol, and sodium disqualifying levels (21 CFR 101.14(a)(4)). Vegetable oil spreads and canola oil-containing foods	Canola oil, vegetable oil spreads, dressings for salads, shortenings and canola-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to canola oil, dressings for salads, and shortenings. When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or canola-oil containing foods, the disclosure statement (i.e., See nutrition information for total fat content)	Limited and not conclusive scientific evidence suggests that eating about 1 1/2 tablespoons (19 grams) of canola oil daily may reduce the risk of coronary heart disease due to the unsaturated fat content in canola oil. To achieve this possible benefit, canola oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams

	must also meet the 10% minimum nutrient content requirement (21 CFR 101.14(e)(6)).	must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself.	of canola oil. *For the purposes of this qualified health claim: (1) "Canola oil" means products that are essentially pure canola oil and are labeled as such. (2) "Vegetable oil spread" means margarine (21 CFR 166.110) and margarine-like products, formulated to contain canola oil. (3) "Dressings for salads" means dressings for salads formulated to contain canola oil. (4) "Shortenings" means vegetable oil shortenings, formulated to contain canola oil. (5) "Canola oil-containing foods" means all other foods, such as sauces or baked goods, formulated to contain canola oil, excluding canola oil, vegetable oil spreads, dressings for salads, and shortenings.

Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease Docket No. 2006P-0243 3/26/2007 enforcement discretion letter	Corn oil (see * for definitions) Vegetable oil blends and shortenings that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), and do not contain more than 4 g of saturated fat per RACC. Dressings for salads (i.e. salad dressings) that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), and do not contain more than 4 g of saturated fat per 50 g. Vegetable oil spreads that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein	Corn oil, vegetable oil blends, vegetable oil spreads, dressings for salads, shortenings and corn-oil containing foods do not need to comply with the total fat disqualifying level in 21 CFR 101.14(a)(4). The requirement that the food comply with the 50 gram-criterion of the saturated fat disqualifying level (21 CFR 101.14(e)(3)) does not apply to corn oil, vegetable oil blends, vegetable oil spreads, and shortenings. The requirement that the food contain a minimum of 10 percent of the Daily Value per RACC of at one of the following: vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per RACC (21 CFR 101.14(e)(6)) does not apply to corn oil, vegetable oil blends, dressings for salads, and shortenings. When the total fat disqualifying level is exceeded in vegetable oil spreads, dressings for salads, shortenings, or corn-oil containing foods, the disclosure statement (i.e., See nutrition information for total fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. When the food does not meet the definition of low saturated fat (21 CFR 101.62(c)(2)), the disclosure statement (i.e., See	Very limited and preliminary scientific evidence suggests that eating about 1 tablespoon (16 grams) of corn oil daily may reduce the risk of heart disease due to the unsaturated fat content in corn oil. FDA concludes that there is little scientific evidence supporting this claim. To achieve this possible benefit, corn oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of corn oil. (1) "corn oil" means products that are essentially pure corn oil and are labeled as such (2) "vegetable oil blends" means a blend of two or more vegetable oils formulated to contain corn oil (3) "vegetable oil spread" means margarine (21 CFR

	or dietary fiber, and do not contain more than 4 g of saturated fat per RACC. Corn oil-containing foods that contain 4 g or more corn oil per RACC, are low in cholesterol (21 CFR 101.62(d)(2)), meet the cholesterol and sodium disqualifying levels (21 CFR 101.14(a)(4)), contain at least 10% of either vitamin A, vitamin C, iron, calcium, protein or dietary fiber. If the RACC of the corn oil-containing food is greater than 30 g, the food cannot contain more than 4 g of saturated fat per RACC, and if the RACC of the corn oil-containing food is 30 g or less, the food cannot contain more than 4 g of saturated fat per 50 g.	nutrition information for saturated fat content) must be placed immediately following the claim, with no intervening material, in the same size, typeface, and contrast as the claim itself. If both of the above two conditions are met, the disclosure statements for total fat and saturated fat can be combined (i.e., See nutrition information for total and saturated fat content).	166.110) and margarine-like products formulated to contain corn oil (4) "dressings for salads" means dressings for salads formulated to contain corn oil (5) "shortenings" means vegetable oil shortenings formulated to contain corn oil (6) "corn oil-containing foods" means all other foods, such as sauces or baked goods, formulated to contain corn oil, excluding corn oil, vegetable oil blends, vegetable oil spreads, dressings for salads, and shortenings.

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XIII. Appendix E: Additional FDA Resources

Contains Nonbinding Recommendations

The following titles are available on FDA's web site.

A Labeling Guide for Restaurants and Other Retail Establishments Selling Away-From-Home Foods

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 Nutrition 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)
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.

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XIV. Appendix F: Calculate the Percent Daily Value for the Appropriate Nutrients

Contains Nonbinding Recommendations

There are two sets of reference values for reporting nutrients in nutrition labeling: 1) Daily Reference Values (DRVs) and 2) Reference Daily Intakes (RDIs). These values assist consumers in interpreting information about the amount of a nutrient that is present in a food and in comparing nutritional values of food products. DRVs are established for adults and children four or more years of age, as are RDIs, with the exception of protein. DRVs are provided for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, potassium, and protein. RDIs are provided for vitamins and minerals and for protein for children less than four years of age and for pregnant and lactating

women. In order to limit consumer confusion, however, the label includes a single term (i.e., Daily Value (DV)), to designate both the DRVs and RDIs. Specifically, the label includes the % DV, except that the % DV for protein is not required unless a protein claim is made for the product or if the product is to be used by infants or children under four years of age. The following table lists the DVs based on a caloric intake of 2,000 calories, for adults and children four or more years of age.

Food Component	**DV**
Total Fat	65 grams (g)
Saturated Fat	20 g
Cholesterol	300 milligrams (mg)
Sodium	2,400 mg
Potassium	3,500 mg
Total Carbohydrate	300 g
Dietary Fiber	25 g
Protein	50 g
Vitamin A	5,000 International Units (IU)
Vitamin C	60 mg
Calcium	1,000 mg
Iron	18 mg
Vitamin D	400 IU
Vitamin E	30 IU
Vitamin K	80 micrograms μg
Thiamin	1.5 mg
Riboflavin	1.7 mg
Niacin	20 mg
Vitamin B_6	2 mg
Folate	400 μg
Vitamin B_{12}	6 μg
Biotin	300 μg

Pantothenic acid	10 mg
Phosphorus	1,000 mg
Iodine	150 μg
Magnesium	400 mg
Zinc	15 mg
Selenium	70 μg
Copper	2 mg
Manganese	2 mg
Chromium	120 μg
Molybdenum	75 μg
Chloride	3,400 mg

In order to calculate the % DV, determine the ratio between the amount of the nutrient in a serving of food and the DV for the nutrient. That is, divide either the actual (unrounded) quantitative amount or the declared (rounded) amount (see next section) by the appropriate DV. When deciding whether to use the unrounded or rounded value, consider the amount that will provide the greatest consistency on the food label and prevent unnecessary consumer confusion. The nutrients in the table above are listed in the order in which they are required to appear on a label in accordance with 21 CFR 101.9(c). This list includes only those nutrients for which a DRV has been established in 21 CFR 101.9(c)(9) or a RDI in 21 CFR 101.9(c)(8)(iv).

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XV. Appendix G: Daily Values for Infants, Children Less Than 4 Years of Age, and Pregnant and Lactating Women

Contains Nonbinding Recommendations

These values have not been codified, but have been published in the Federal Register to provide guidance to manufacturers for the nutrients listed (58 FR 2206 at 2213; January 6, 1993). The abbreviation "IU" is used for International Units, "mg" for milligrams, and "mcg" for micrograms. The abbreviation "μg" may also be used for micrograms. Also, the agency has modified the units of measure for four nutrients. Calcium and phosphorus values are expressed in mg and biotin and folate values in mcg (60 FR 67164 to 67174).

Vitamin or Mineral	Infants	Less than 4 Years	Pregnant and Lactating Women	Units of Measure
Vitamin A	1,500	2,500	8,000	IU
Vitamin C	35	40	60	mg
Calcium	600	800	1,300	mg
Iron	15	10	18	mg
Vitamin D	400	400	400	IU
Vitamin E	5	10	30	IU
Thiamin	0.5	0.7	1.7	mg
Riboflavin	0.6	0.8	2.0	mg
Niacin	8	9	20	mg
Vitamin B6	0.4	0.7	2.5	mg
Folate	100	200	800	mcg
Vitamin B12	2	3	8	mcg
Biotin	50	150	300	mcg
Pantothenic acid	3	5	10	mg
Phosphorus	500	800	1,300	mg

Iodine	45	70	150	mcg
Magnesium	70	200	450	mg
Zinc	5	8	15	mg
Copper	0.6	1.0	2.0	mg

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XVI. Appendix H: Rounding the Values According to FDA Rounding Rules

Contains Nonbinding Recommendations

The following table provides rounding rules for declaring nutrients on the nutrition label or in labeling:

Nutrient	Increment Rounding	Insignificant Amount
Calories Calories from Fat Calories from Saturated Fat	< 5 cal - express as 0 ≤50 cal - express to nearest 5 cal increment > 50 cal - express to nearest 10 cal increment	< 5 cal
Total Fat Saturated Fat	< .5 g - express as 0 < 5 g - express to nearest .5g increment	< .5 g

Trans Fat Polyunsaturated Fat Monounsaturated Fat	≥5 g - express to nearest 1 g increment	
Cholesterol	< 2 mg - express as 0 2 - 5 mg - express as "less than 5 mg" > 5 mg - express to nearest 5 mg increment	< 2 mg
Sodium Potassium	< 5 mg - express as 0 5 - 140 mg - express to nearest 5 mg increment > 140 mg - express to nearest 10 mg increment	< 5 mg
Total Carbohydrate Dietary Fiber	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" ≥1 g - express to nearest 1 g increment	< 1 g
Soluble and Insoluble Fiber Sugars Sugar Alcohol Other Carbohydrate	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" ≥1 g - express to nearest 1 g increment	< .5 g
Protein	< .5 g - express as 0 < 1 g - express as "Contains less than 1 g" or "less than 1 g" or to 1 g if .5 g to < 1 g ≥1 g - express to nearest 1 g increment	< 1 g
When declaring nutrients other than vitamins and minerals that have RDIs as a % DV	express to nearest 1% DV increment	< 1% DV
Vitamins & Minerals (express as % DV)	< 2% of RDI may be expressed as: (1) 2% DV if actual amount is 1% or more (2) 0 (3) an asterisk that refers to statement "Contains less than 2% of the Daily Value of this (these) nutrient(s)" (4) for Vit A, C, calcium, iron: statement "Not a significant source of _____ (listing the vitamins and minerals omitted)" ≤10% of RDI - express to nearest 2% DV increment > 10% - 50% of RDI - express to nearest	< 2% RDI

	5% DV increment > 50% of RDI - express to nearest 10% DV increment	
Beta-Carotene (express as % DV)	≤10% of RDI for vitamin A- express to nearest 2% DV increment > 10% - 50% of RDI for vitamin A- express to nearest 5% DV increment > 50% of RDI for vitamin A- express to nearest 10% DV increment	

To express nutrient values to the nearest 1 g increment, for amounts falling exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.99 g), round up (e.g., 3 g). For amounts less than halfway between two whole numbers (e.g, 2.01 g to 2.49 g), round down (e.g., 2 g).

When rounding % DV for nutrients other than vitamins and minerals, when the % DV values fall exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.99), the values round up (e.g., 3 %). For values less than halfway between two whole numbers (e.g., 2.01 to 2.49), the values round down (e.g., 2%).