

U.S. Food and Drug Administration
Protecting and Promoting Your Health

Guidance for Industry: A Food Labeling Guide (7. Nutrition Labeling; Questions G1 through P8)

January 2013

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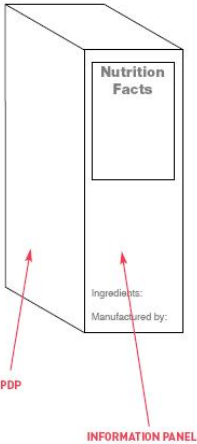
The document below is available in several foreign language(s). FDA offers these translations as a service to a broad international audience. We hope that you find these translations useful. While the agency has attempted to obtain translations that are as faithful as possible to the English version, we recognize that the translated versions may not be as precise, clear, or complete as the English version. The official version of this document is the English version.

- [General](#)
- [Nutrient Declaration](#)
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- [Label Formats/Graphics](#) ([/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064904.htm](#))

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. [21 CFR 101.2\(b\) & \(e\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_12](#)) & [101.9\(i\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#))



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. [21 CFR 101.9\(d\)\(1\)\(i\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#))

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. [21 CFR 101.9\(c\) & \(d\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#))

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 the example in [21 CFR 101.9\(d\)\(1\)](#) or (2) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#)) 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. [21 CFR 101.9\(d\)\(1\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#))

Nutrient Declaration

N1. Are Nutrition Facts labels required on all foods?

Answer: The Nutrition Facts label (an example is illustrated in section 7 L2) is required on most food packages labeled. The illustration indicates FDA's typeface and style to help assure readability and conspicuousness. Not all of these type specifications are required. The mandatory type specifications are listed in [21 CFR 101.9\(d\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#)). 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 should extend the width of the Nutrition Facts box, 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\(a\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#)) and [21 CFR 101.9\(a\)\(1\)](#) ([http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19](#))

Below are listed categories providing exemptions or special provisions for nutrition labeling. Generally, a food package loses those exemptions, 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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
*Food served in restaurants, etc. or delivered to homes ready for immediate consumption	21 CFR 101.9(j)(2) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

	gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
*Delicatessen-type food, bakery products and confections that are sold directly to consumers from the location where prepared	21 CFR 101.9(j)(3) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
*Foods that provide no significant nutrition such as instant coffee (plain, unsweetened) and most spices	21 CFR 101.9(j)(4) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
Dietary supplements (must comply with 21 CFR 101.36 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=563f0b6235da3f4c7912a64cbceec305&rgn=div8&view=text&node=21:2.0.1.1.2.3.1.1&idno=211))	21 CFR 101.9(j)(6) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
Medical foods	21 CFR 101.9(j)(8) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
Bulk foods shipped for further processing or packaging before retail sale	21 CFR 101.9(j)(9) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) and 101.45 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=563f0b6235da3f4c7912a64cbceec305&rgn=div8&view=text&node=21:2.0.1.1.2.3.1.5&idno=211)
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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
Certain egg cartons (nutrition information inside lid or on insert in carton)	21 CFR 101.9(j)(14) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
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) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)
Game meats may provide required nutrition information or labeling in accordance with 21 CFR 101.9(a)(2) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)	21 CFR 101.9(j)(12) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

N2. Are nutrition designations permitted on food package labels?

Answer: FDA considers information that is required or permitted in the Nutrition Facts label that is on the front label or elsewhere on the package outside the Nutrition Facts label 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\(c\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_113\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_113)

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

Answer: In addition to the nutrients shown on the label in section 7 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\(c\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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\(c\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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\(a\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19), [21 CFR 101.9\(c\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19), [21 CFR 101.9\(c\)\(8\)\(ii\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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\(c\)\(8\)\(ii\)\(A\)-\(B\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) and [21 CFR 101.9\(c\)\(8\)\(iv\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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. [21 CFR 101.9\(c\)\(1\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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\(c\)\(1\) \(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4b149f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) 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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19). 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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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. **21 CFR 101.9(c)(1)(i)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19), **21 CFR 101.9(c)(2)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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 0.5 gram increments rounded to the nearest 1/2 gram.

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

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

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

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. **21 CFR 101.9(c)(8)(iv) & (c)(9)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19). 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 of the sample of food. **21 CFR 101.9(c)(6)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

N17. Does total carbohydrate include dietary fiber?

Answer: Yes. Dietary fiber must be listed as a subcomponent under total carbohydrate. **21 CFR 101.9(c)(6)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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. **21 CFR 101.9(c)(6)(ii)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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)(ii)**) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19). **21 CFR 101.9(c)(6)(i)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19), **21 CFR 101.9(c)(7)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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. **21 CFR 101.9(c)(7)(ii)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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. [21 CFR 101.9\(d\)\(9\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

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\(c\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) and summarized in Appendix H.

N26. 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 in the order listed in [21 CFR 101.9\(c\)\(8\)\(iv\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) [21 CFR 101.9\(c\)\(5\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

(http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) and [21 CFR 101.9\(d\)\(8\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

N27. 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.

N28. 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 or percent of a nutrient (eg. 300 mg omega 3) and may not characterize the level of the nutrient (you may not state "High in Omega-3"). [21 CFR 101.13\(i\)\(3\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_113) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_113)

N29. 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\(h\)\(4\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) [21 CFR 101.9\(e\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

N30. 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.

N31. 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. [21 CFR 101.9\(g\)](http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19)

N32. 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."

N33. 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.

N34. Does FDA 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.

N35. 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 for nutrient analysis, FDA uses appropriate methods published by the Association of Analytical Chemists (AOAC) in *Official Methods of Analysis of the AOAC International* (the most current edition unless otherwise stated in the CFR) or other methods as needed. You may wish to ascertain if the laboratory is familiar with these methodologies when selecting a laboratory.

N36. 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.

N37. 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

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

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) 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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19) which:

1. allows nutrition information to be placed on the label of the outer package or in labeling within or attached to the outer 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)** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19). 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 (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19), (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)**) (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_19).
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** (http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=4bf49f997b04dcacdfbd637db9aa5839&ty=HTML&h=L&mc=true&n=pt21.2.101&r=PART#se21.2.101_145), 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 individual food product 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.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

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