

**TITLE 21 – FOOD AND DRUGS**

**CHAPTER 1 – FOOD AND DRUG ADMINISTRATION,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**SUBCHAPTER B – FOOD FOR HUMAN CONSUMPTION**

**PART 101 – FOOD LABELING**

**SUBPART D – SPECIFIC REQUIREMENTS FOR NUTRIENT CONTENT CLAIMS**

*21 CFR 101.65*

## **§ 101.65 Implied nutrient content claims and related label statements.**

(a) General requirements. An implied nutrient content claim can only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms described in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with §101.9, §101.10, or §101.36, as applicable.

(b) Label statements that are not implied claims. Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under §101.13(b)(2). The following types of label statements are generally not implied nutrient content claims and, as such, are not subject to the requirements of § 101.13 and this section:

(1) A claim that a specific ingredient or food component is absent from a product, provided that the purpose of such claim is to facilitate avoidance of the substances because of food allergies (see § 105.62 of this chapter), food intolerance, religious beliefs, or dietary practices such as vegetarianism or other non-nutrition related reason, e.g., “100 percent milk free;”

(2) A claim about a substance that is nonnutritive or that does not have a nutritive function, e.g., “contains no preservatives,” “no artificial colors;”

(3) A claim about the presence of an ingredient that is perceived to add value to the product, e.g., “made with real butter,” “made with whole fruit,” or “contains honey,” except that claims about the presence of ingredients other than vitamins or minerals or that are represented as a source of vitamins and minerals are not allowed on labels or in labeling of dietary supplements of vitamins and minerals that are not in conventional food form.

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food (e.g., “corn oil,” “oat bran,” “dietary supplement of vitamin C 60 mg tablet”).

(5) A statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient benefit (e.g., “corn oil margarine,” “oat bran muffins,” or “whole wheat bagels”), unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount; and

(6) A label statement made in compliance with a specific provision of part 105 of this chapter, solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition, where the claim identifies the special diet of which the food is intended to be a part.

(c) Particular implied nutrient content claims. (1) Claims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount (e.g., “high in oat bran”) are implied nutrient content claims and must comply with paragraph (a) of this section.

(2) The phrases “contains the same amount of [nutrient] as a [food]” and “as much [nutrient] as a [food]” may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a “good source” of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., “as much fiber as an apple,” “Contains the same amount of Vitamin C as an 8 oz. glass of orange juice.”).

(3) Claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either “low” in or a “good source” of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., “high in...”), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of

dietary fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

(d) *General nutritional claims.* (1) This paragraph covers labeling claims that are implied nutrient content claims because they:

(i) Suggest that a food because of its nutrient content may help consumers maintain healthy dietary practices; and

(ii) Are made in connection with an explicit or implicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams of fat”).

(2) You may use the term “healthy” or related terms (e.g., “health,” “healthful,” “healthfully,” “healthfulness,” “healthier,” “healthiest,” “healthily,” and “healthiness”) as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

(i) The food meets the following conditions for fat, saturated fat, cholesterol, and other nutrients:

If the food is...	The fat level must be...	The saturated fat level must be...	The cholesterol level must be...	The food must contain...
(A) A raw fruit or vegetable	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(B) A single-ingredient or a mixture of frozen or canned fruits and vegetables <sup>1</sup>	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(C) An enriched cereal-grain product that conforms to a standard of identity in part 136, 137 or 139 of this chapter	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	N/A
(D) A raw, single-ingredient seafood or game meat	Less than 5 grams (g) total fat per RA <sup>2</sup> and per 100 g	Less than 2 g saturated fat per RA and per 100 g	Less than 95 mg cholesterol per RA and per 100 g	At least 10 percent of the RDI <sup>3</sup> or the DRV <sup>4</sup> per RA of one or more of vitamin A, vitamin C, calcium, iron, protein, or fiber
(E) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	Low fat as defined in § 101.62(b)(3)	Low saturated fat as defined in § 101.62(c)(3)	90 mg or less cholesterol per LS <sup>5</sup>	At least 10 percent of the RDI or DRV per LS of two nutrients (for a main dish product) or of three nutrients (for a meal product) of: vitamin A, vitamin C, calcium, iron, protein, or fiber
(F) A food not specifically listed in this table	Low fat as defined in § 101.62(b)(2)	Low saturated fat as defined in § 101.62(c)(2)	The disclosure level for cholesterol specified in § 101.13(h) or less	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein or fiber

<sup>1</sup> May include ingredients whose addition does not change the nutrient profile of the fruit or vegetable.

<sup>2</sup> RA means Reference Amount Customarily Consumed per Eating Occasion (§ 101.12(b)).

<sup>3</sup> RDI means Reference Daily Intake (§101.9(c)(8)(iv)).

<sup>4</sup> DRV means Daily Reference Value (§101.9(c)(9)).

<sup>5</sup> LS means Labeled Serving, i.e., the serving size that is specified in the nutrition information on the product label (§ 101.9(b)).

(ii) The food meets the following conditions for sodium:

If the food is...	The sodium level must be...
(A) A food with a RA that is greater than 30 g or 2 tablespoons (tbsp.)	480 or less sodium per RA and per LS
(B) A food with a RA that is equal to or less than 30 g or 2 tbsp.	480 mg or less sodium per 50 g <sup>1</sup>
(C) A meal product as defined in § 101.13(l) or a main dish product as defined in § 101.13(m)	600 mg or less sodium per LS

(iii) The food complies with the definition and declaration requirements in this part 101 for any specific nutrient content claim on the label or in labeling, and

(iv) If you add a nutrient to the food specified in paragraphs (d)(2)(i)(D), (d)(2)(i)(E), or (d)(2)(i)(F) of this section to meet the 10 percent requirement, that addition must be in accordance with the fortification policy for foods in § 104.20 of this chapter.

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<sup>1</sup> For dehydrated food that is typically reconstituted with water or a liquid that contains insignificant amounts of RA of all nutrients (as defined in § 101.9(f)(1)), the 50 g refers to the “prepared” form of the product.