

Health and Human Services (DHHS), Government Printing Office (GPO);

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment;

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or “Nutrition and Your Health: Dietary Guidelines for Americans,” USDA and DHHS, GPO.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and reduced risk of heart disease:

(1) Soluble fiber from foods such as [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the 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] supplies _____ grams of the [grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] soluble fiber from [name of the soluble fiber source from paragraph (c)(2)(ii) of this section] necessary per day to have this effect.

(2) Diets low in saturated fat and cholesterol that include [_____ grams of soluble fiber specified in paragraph (c)(2)(i)(G) of this section] of soluble fiber per day from [name of soluble fiber source from paragraph (c)(2)(ii) of this section and, if desired, the name of the food product] may reduce the risk of heart disease. One serving of [name of food] provides _____ grams of this soluble fiber.

[62 FR 3600, Jan. 23, 1997, as amended at 62 FR 15344, Mar. 31, 1997; 63 FR 8119, Feb. 18, 1998]

Subpart F—Specific Requirements for Descriptive Claims That Are Neither Nutrient Content Claims nor Health Claims

§ 101.93 Notification procedures for certain types of statements on dietary supplements.

(a)(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Special Nutritionals (HFS-450), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

(ii) The text of the statement that is being made;

(iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement; and

(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears.

(3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

(b) *Disclaimer.* The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and the manufacturer, packer, or distributor wishes to

take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6) of the act.

(c) *Text for disclaimer.* (1) Where there is one statement, the disclaimer shall be placed in accordance with paragraph (d) of this section and shall state:

This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d) *Placement.* The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e) *Typesize.* The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

[62 FR 49886, Sept. 23, 1997, as amended at 62 FR 49867, Sept. 23, 1997]

§ 101.95 “Fresh,” “freshly frozen,” “fresh frozen,” “frozen fresh.”

The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms as described in paragraphs (a) and (b) of this section that expressly or implicitly refers to the food on labels or labeling, including

use in a brand name and use as a sensory modifier. However, the use of the term “fresh” on labels or labeling is not subject to the requirements of paragraph (a) of this section if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term “fresh” used to describe pasteurized whole milk is not subject to paragraph (a) of this section because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term “fresh” to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to paragraph (a) of this section because the term implies that the food is not processed or preserved. Uses of fresh not subject to this regulation will be governed by the provisions of 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(a) The term “fresh,” when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.

(b) The terms “fresh frozen” and “frozen fresh,” when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). Blanching of the food before freezing will not preclude use of the term “fresh frozen” to describe the food. “Quickly frozen” means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(c) *Provisions and restrictions.* (1) The following do not preclude the food from use of the term “fresh:”

- (i) The addition of approved waxes or coatings;
- (ii) The post-harvest use of approved pesticides;
- (iii) The application of a mild chlorine wash or mild acid wash on produce; or