notice in the FEDERAL REGISTER informing the public of such fact.

[58 FR 2413, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993, as amended at 58 FR 44033, Aug. 18, 1993; 62 FR 40598, July 29, 1997; 63 FR 26718, May 14, 1998; 63 FR 40024, July 27, 1998; 67 FR 9585, Mar. 4, 2002; 69 FR 16481, Mar. 30, 2004]

Subpart E—Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug Administration (FDA) to issue a regulation regarding a health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with §56.104 or §56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

(Date)_____
Name of petitioner _____
Post office address _____
Subject of the petition _____
Food and Drug Administration,
Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800),
5100 Paint Branch Pkwy.,
College Park, MD 20740,

The undersigned, _____ submits this petition pursuant to section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

Attached hereto, and constituting a part of this petition, are the following:

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of §101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of §101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS),

listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term ''substance'' in §101.14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the AOAC INTERNATIONAL (AOAC), where available. If no AOAC method is available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under §25.30 or §25.32 of this chapter or an environmental assessment under §25.40 of this chapter.

Yours very truly,
Petitioner _____
By _____
(Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner

or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(i) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in ''B. Summary of Scientific Data'' if the information in ''A. Preliminary Requirements'' is inadequate in explaining how the substance conforms to the requirements of §101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. If FDA does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. A petition that has been denied, or has been deemed to be denied, without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by letter of notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the FEDERAL REGISTER. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for the requested use of the health claim in the FEDERAL REGISTER within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

(iii) If FDA does not act within 90 days of the date of filing, the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

(4)(i) Within 270 of the date of publication of the proposal, FDA will publish a final rule that either authorizes use of the health claim or explains why the agency has decided not to authorize one.

(ii) For cause, FDA may extend, no more than twice, the period in which it will publish a final rule; each such extension will be for no more than 90 days. FDA will publish a notice of each extension in the FEDERAL REGISTER. The document will state the basis for the extension, the length of the extension, and the date by which the final rule will be published, which date shall be within 540 days of the date of receipt of the petition.

[58 FR 2534, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993, as amended at 59 FR 425, Jan. 4, 1994; 62 FR 28232, May 22, 1997; 62 FR 40599, July 29, 1997; 63 FR 26719, May 14, 1998; 63 FR 40024, July 27, 1998; 66 FR 56035, Nov. 6, 2001]

§ 101.71 Health claims: claims not authorized.

Health claims not authorized for foods in conventional food form or for dietary supplements of vitamins, minerals, herbs, or other similar substances:

(a) Dietary fiber and cardiovascular disease.

(b) Zinc and immune function in the elderly.

[58 FR 2534, Jan. 6, 1993, as amended at 58 FR 2548, 2578, 2620, 2639, 2664, 2714, Jan. 6, 1993; 58 FR 17100, Apr. 1, 1993; 59 FR 437, Jan. 4, 1994; 65 FR 58918, Oct. 3, 2000]

§ 101.72 Health claims: calcium, vitamin D, and osteoporosis.

(a) *Relationship between calcium, vitamin D, and osteoporosis.* An inadequate intake of calcium or calcium and vitamin D contributes to low peak bone mass, which has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. Vitamin D is required for normal absorption of calcium and to prevent the occurrence of high serum parathyroid hormone (PTH) concentration, which stimulates mobilization of calcium from the skeleton and can lower bone mass. Calcium, along with vitamin D and several other nutrients, is required for normal bone mineralization. While vitamin D is required for optimal bone mineralization, it is more effective when calcium intake is adequate. An adequate intake of calcium and vitamin D is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which adequate intakes of calcium and vitamin D and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of adequate intakes of calcium and vitamin D later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause, but a significant protective effect is also seen among men and younger women.

(b) *Significance of calcium or calcium and vitamin D.* Adequate calcium intake, or adequate calcium and vitamin D intake, is not the only recognized risk factor in the development of osteoporosis, which is a multifactorial bone disease. Maintenance of adequate calcium and vitamin D intakes throughout life is necessary to achieve optimal peak bone mass and to reduce the risk of osteoporosis in later life. However, vitamin D is most effective in this regard when calcium intake is adequate. Increasing intake of calcium has been shown to have beneficial effects on bone health independent of dietary vitamin D.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating calcium or, when appropriate, calcium and vitamin D with a reduced risk of osteoporosis may be made on the label or labeling of a food described in paragraphs (c)(2)(ii) and (d)(1) of this section, provided that:

(A) The claim makes clear the importance of adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, throughout life, in a healthful diet, are essential to reduce osteoporosis risk. The claim does not imply that adequate calcium intake, or when appropriate, adequate calcium and vitamin D intake, is the only recognized risk factor for the development of osteoporosis;

(B) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate dietary calcium intake, or when appropriate, an adequate dietary calcium and vitamin D intake, throughout life.

(ii) *Nature of the food.* (A) The food shall meet or exceed the requirements for a ''high'' level of calcium as defined in § 101.54(b);

(B) The calcium content of the product shall be assimilable;

(C) Dietary supplements shall meet the United States Pharmacopeia (USP)

standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no USP standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label;

(D) A food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

(d) *Optional information.* (1) The claim may include the term ''vitamin D'' if the food meets or exceeds the requirements for a ''high'' level of vitamin D as defined in §101.54(b);

(2) The claim may include information from paragraphs (a) and (b) of this section.

(3) The claim may make reference to physical activity.

(4) The claim may include information on the number of people in the United States, including the number of people in certain subpopulations in the United States, who have osteoporosis or low bone density. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or the National Osteoporosis Foundation.

(5) The claim may state that the role of adequate calcium intake, or when appropriate, the role of adequate calcium and vitamin D intake, throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase ''build and maintain good bone health'' may be used to convey the concept of optimizing peak bone mass. The claim may also state that adequate intake of calcium, or when appropriate, adequate intake of calcium and vitamin D, is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss for persons with a family history of the disease, post-menopausal women, and elderly men and women.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between calcium and osteoporosis:

Adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

(f) *Model additional health claims for calcium and vitamin D.* The following model health claims may be used in food labeling to describe the relationship between calcium, vitamin D, and osteoporosis:

Adequate calcium and vitamin D throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis.

Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis in later life.

[73 FR 56486, Sept. 29, 2008]

§101.73 Health claims: dietary lipids and cancer.

(a) *Relationship between fat and cancer.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Among dietary factors, the strongest positive association has been found between total fat intake and risk of some types of cancer. Based on the totality of the publicly available scientific evidence, there is significant scientific agreement among experts, qualified by training and experience to evaluate such evidence, that diets high in total fat are associated with an increased cancer risk. Research to date, although not conclusive, demonstrates that the total amount of fats, rather than any specific type of fat, is positively associated with cancer risk. The mechanism by which total fat affects cancer has not yet been established.

(3) A question that has been the subject of considerable research is whether

the effect of fat on cancer is site-specific. Neither human nor animal studies are consistent in the association of fat intake with specific cancer sites.

(4) Another question that has been raised is whether the association of total fat intake to cancer risk is independently associated with energy intakes, or whether the association of fat with cancer risk is the result of the higher energy (caloric) intake normally associated with high fat intake. FDA has concluded that evidence from both animal and human studies indicates that total fat intake alone, independent of energy intake, is associated with cancer risk.

(b) *Significance of the relationship between fat intake and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and high in calories. The average U.S. diet is estimated to contain 36 to 37 percent of calories from total fat. Current dietary guidelines from the Federal Government and other national health professional organizations recommend that dietary fat intake be reduced to a level of 30 percent or less of energy (calories) from total fat. In order to reduce intake of total fat, individuals should choose diets which are high in vegetables, fruits, and grain products (particularly whole grain products), choose lean cuts of meats, fish, and poultry, substitute low-fat dairy products for higher fat products, and use fats and oils sparingly.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in fat with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat ''may'' or ''might'' reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: ''some types of cancer'' or ''some cancers'';

(C) In specifying the nutrient, the claim uses the term ''total fat'' or ''fat'';

(D) The claim does not specify types of fat or fatty acid that may be related to the risk of cancer;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat; and

(F) The claim indicates that the development of cancer depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of §101.62 for a ''low fat'' food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, ostrich) may meet the requirements for ''extra lean'' in §101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The claim may include information from paragraphs (a) and (b) of this section which summarize the relationship between dietary fat and cancer and the significance of the relationship.

(3) The claim may indicate that it is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must 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, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between dietary fat and cancer:

(1) Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

(2) Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking, and what you eat.

[58 FR 2801, Jan. 6, 1993; 58 FR 17343, Apr. 2, 1993]

§ 101.74 Health claims: sodium and hypertension.

(a) *Relationship between sodium and hypertension (high blood pressure).* (1) Hypertension, or high blood pressure, generally means a systolic blood pressure of greater than 140 millimeters of mercury (mm Hg) or a diastolic blood pressure of greater than 90 mm Hg. Normotension, or normal blood pressure, is a systolic blood pressure below 140 mm Hg and diastolic blood pressure below 90 mm Hg. Sodium is specified here as the chemical entity or electrolyte ''sodium'' and is distinguished from sodium chloride, or salt, which is 39 percent sodium by weight.

(2) The scientific evidence establishes that diets high in sodium are associated with a high prevalence of hypertension or high blood pressure and with increases in blood pressure with age, and that diets low in sodium are associated with a low prevalence of hypertension or high blood pressure and with a low or no increase of blood pressure with age.

(b) *Significance of sodium in relation to high blood pressure.* (1) High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke. Early management of high blood pressure is a major public health goal that can assist in reducing mortality associated with coronary heart disease and stroke. There is a continuum of mortality risk that increases as blood pressures rise. Individuals with high blood pressure are at greatest risk, and individuals with moderately high, high normal, and normal blood pressure are at steadily decreasing risk. The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. There is also evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well.

(2) The populations at greatest risk for high blood pressure, and those most likely to benefit from sodium reduction, include those with family histories of high blood pressure, the elderly, males because they develop hypertension earlier in life than females, and black males and females. Although some population groups are at greater risk than others, high blood-pressure is a disease of public health concern for all population groups. Sodium intake, alcohol consumption, and obesity are identified risk factors for high blood pressure.

(3) Sodium intakes exceed recommended levels in almost every group in the United States. One of the major public health recommendations relative to high blood pressure is to decrease consumption of salt. On a population-wide basis, reducing the average sodium intake would have a small but significant effect on reducing the average blood pressure, and, consequently, reducing mortality from coronary heart disease and stroke.

(4) Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 milligrams (mg) sodium per day and an upper level of 2,400 mg sodium per day, the FDA Daily Value for sodium.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in sodium with reduced risk of high blood pressure may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in sodium ''may'' or ''might'' reduce the risk of high blood pressure;

(B) In specifying the disease, the claim uses the term ''high blood pressure'';

(C) In specifying the nutrient, the claim uses the term ''sodium'';

(D) The claim does not attribute any degree of reduction in risk of high blood pressure to diets low in sodium; and

(E) The claim indicates that development of high blood pressure depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of §101.61 for a ''low sodium'' food.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of high blood pressure in addition to dietary sodium consumption: Family history of high blood pressure, growing older, alcohol consumption, and excess weight.

(2) The claim may include information from paragraphs (a) and (b) of this section, which summarizes the relationship between dietary sodium and high blood pressure and the significance of the relationship.

(3) The claim may include information on the number of people in the United States who have high blood pressure. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Health and Human Services (DHHS) and U.S. Department of Argiculture (USDA), Government Printing Office.

(4) The claim may indicate that it is consistent with ''Nutrition and Your Health: U.S. Dietary Guidelines for Americans, DHHS and USDA, Government Printing Office.

(5) In specifying the nutrient, the claim may include the term ''salt'' in addition to the term ''sodium.''

(6) In specifying the disease, the claim may include the term ''hypertension'' in addition to the term ''high blood pressure.''

(7) The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment. If the claim defines high or normal blood pressure, then the health claim must state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary sodium and high blood pressure:

(1) Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

(2) Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

[58 FR 2836, Jan. 6, 1993; 58 FR 17100, Apr. 1, 1993]

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

(a) *Relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams/decaliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(b) *Significance of the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals. There is also evidence that reducing saturated fat and cholesterol intakes in persons with blood cholesterol levels in the normal range also reduces risk of heart disease.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol with reduced risk of coronary heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section provided that:

(A) The claim states that diets low in saturated fat and cholesterol ''may'' or ''might'' reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the terms ''heart disease'' or ''coronary heart disease;''

(C) In specifying the nutrient, the claim uses the terms ''saturated fat'' and ''cholesterol'' and lists both;

(D) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in dietary saturated fat and cholesterol; and

(E) The claim states that coronary heart disease risk depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.62 for a ''low saturated fat,'' ''low cholesterol,'' and ''low fat'' food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for ''extra lean'' in § 101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: A family history of coronary heart disease, elevated blood total and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of saturated fat and cholesterol to heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total- and LDL cholesterol.''

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term ''total fat'' in addition to the terms ''saturated fat'' and ''cholesterol''.

(5) The claim may include information on the number of people in the United States who have coronary 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,'' U.S. Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA), Government Printing Office.

(6) The claim may indicate that it is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' DHHS and USDA, Government Printing Office.

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

(e) *Model health claims.*The following are model health claims that may be used in food labeling to describe the relationship between dietary saturated fat and cholesterol and risk of heart disease:

(1) While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease;

(2) Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles;

(3) Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease;

(4) Many factors, such as a family history of the disease, increased blood- and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes, and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol, and total fat may help reduce the risk of heart disease; and

(5) Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.

[58 FR 2757, Jan. 6, 1993]

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

(a) *Relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include: A family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The scientific evidence establishes that diets low in fat and high in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets low in fat and high in fiber-containing foods are associated with reduced risk of some types of cancer.

(b) *Significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in grain products, fruits, and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily), and grain products (six or more servings daily).

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in fat and high in fiber-containing grain products, fruits, and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fiber-containing grain products, fruits, and vegetables ''may'' or ''might'' reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: ''some types of cancer,'' or ''some cancers'';

(C) The claim is limited to grain products, fruits, and vegetables that contain dietary fiber;

(D) The claim indicates that development of cancer depends on many factors;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fiber-containing grain products, fruits, and vegetables;

(F) In specifying the dietary fiber component of the labeled food, the claim uses the term ''fiber'', ''dietary fiber'' or ''total dietary fiber''; and

(G) The claim does not specify types of dietary fiber that may be related to risk of cancer.

(ii) *Nature of the food.* (A) The food shall be or shall contain a grain product, fruit, or vegetable.

(B) The food shall meet the nutrient content requirements of §101.62 for a ''low fat'' food.

(C) The food shall meet, without fortification, the nutrient content requirements of §101.54 for a ''good source'' of dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables, and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer causing chemicals, and dietary factors.

(3) The claim may indicate that it is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must 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, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk:

(1) 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.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits, and vegetables that contain dietary fiber may reduce your risk of some cancers.

[58 FR 2548, Jan. 6, 1993]

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(a) *Relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(3) Populations with relatively low blood cholesterol levels tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fruits, vegetables, and grain products. Although the specific roles of these plant foods are not yet fully understood, many studies have shown that diets high in plant foods are associated with reduced risk of coronary heart disease. These studies correlate diets rich in fruits, vegetables, and grain products and nutrients from these diets, such as some types of fiber, with reduced coronary heart disease risk. Persons consuming these diets frequently have high intakes of dietary fiber, particularly soluble fibers. Currently, there is not scientific agreement as to whether a particular type of soluble fiber is beneficial, or whether the observed protective effects of fruits, vegetables, and grain products against heart disease are due to other components, or a combination of components, in these diets, including, but not necessarily limited to, some types of soluble fiber, other fiber components, other characteristics of the complex carbohydrate content of these foods, other nutrients in these foods, or displacement of saturated fat and cholesterol from the diet.

(b) *Significance of the relationship between diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals, including persons with blood cholesterol levels in the normal range. Additionally, consuming diets high in fruits, vegetables, and grain products, foods that contain soluble fiber, may be a useful adjunct to a low saturated fat and low cholesterol diet.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. Intakes of fiber-containing fruits, vegetables, and grain products are about half of recommended intake levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Recommended total dietary fiber intakes are about 25 grams (g) daily, of which about 25 percent (about 6 g) should be soluble fiber.

(4) Current dietary guidance recommendations encourage decreased consumption of dietary fat, especially saturated fat and cholesterol, and increased consumption of fiber-rich foods to help lower blood LDL-cholesterol levels. Results of numerous studies have shown that fiber-containing fruits, vegetables, and grain products can help lower blood LDL-cholesterol.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber ''may'' or ''might'' reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: ''heart disease'' or ''coronary heart disease;''

(C) The claim is limited to those fruits, vegetables, and grains that contain fiber;

(D) In specifying the dietary fiber, the claim uses the term ''fiber,'' ''dietary fiber,'' ''some types of dietary fiber,'' ''some dietary fibers,'' or ''some fibers;'' the term ''soluble fiber'' may be used in addition to these terms;

(E) In specifying the fat component, the claim uses the terms ''saturated fat'' and ''cholesterol;'' and

(F) The claim indicates that development of heart disease depends on many factors; and

(G) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit, vegetable, or grain product.

(B) The food shall meet the nutrient content requirements of §101.62 for a ''low saturated fat,'' ''low cholesterol,'' and ''low fat'' food.

(C) The food contains, without fortification, at least 0.6 g of soluble fiber per reference amount customarily consumed;

(D) The content of soluble fiber shall be declared in the nutrition information panel, consistent with §101.9(c)(6)(i)(A).

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease, elevated blood-, total- and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber to heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total- and LDL-cholesterol.''

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in saturated fat and cholesterol and high in fruits,

vegetables, and grain products that contain fiber and coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term ''total fat'' in addition to the terms ''saturated fat'' and ''cholesterol.''

(5) The claim may indicate that it is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of 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 claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber:

(1) 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.

(2) Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

[58 FR 2578, Jan. 6, 1993]

§ 101.78 Health claims: fruits and vegetables and cancer.

(a) *Relationship between substances in diets low in fat and high in fruits and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, many studies have shown that diets high in plant foods are associated with reduced risk of some types of cancers. These studies correlate diets rich in fruits and vegetables and nutrients from these diets, such as vitamin C, vitamin A, and dietary fiber, with reduced cancer risk. Persons consuming these diets frequently have high intakes of these nutrients. Currently, there is not scientific agreement as to whether the observed protective effects of fruits and vegetables against cancer are due to a combination of the nutrient components of diets rich in fruits and vegetables, including but not necessarily limited to dietary fiber, vitamin A (as beta-carotene) and vitamin C, to displacement of fat from such diets, or to intakes of other substances in these foods which are not nutrients but may be protective against cancer risk.

(b) *Significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in fruits and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These

diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber, vitamin A (as beta-carotene), and vitamin C. Current dietary guidelines from Federal Government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (5 or more servings daily), particularly those fruits and vegetables which contain dietary fiber, vitamin A, and vitamin C.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating substances in diets low in fat and high in fruits and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fruits and vegetables ''may'' or ''might'' reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: ''some types of cancer'', or ''some cancers'';

(C) The claim characterizes fruits and vegetables as foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber;

(D) The claim characterizes the food bearing the claim as containing one or more of the following, for which the food is a good source under §101.54: dietary fiber, vitamin A, or vitamin C;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fruits and vegetables;

(F) In specifying the fat component of the labeled food, the claim uses the term ''total fat'' or ''fat'';

(G) The claim does not specify types of fats or fatty acids that may be related to risk of cancer;

(H) In specifying the dietary fiber component of the labeled food, the claim uses the term ''fiber'', ''dietary fiber'', or ''total dietary fiber'';

(I) The claim does not specify types of dietary fiber that may be related to risk of cancer; and

(J) The claim indicates that development of cancer depends on many factors.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit or vegetable.

(B) The food shall meet the nutrient content requirements of §101.62 for a ''low fat'' food.

(C) The food shall meet, without fortification, the nutrient content requirements of §101.54 for a ''good source'' of at least one of the following: vitamin A, vitamin C, or dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fruits and vegetables and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(3) The claim may use the word ''beta-carotene'' in parentheses after the term vitamin A, provided that the vitamin A in the food bearing the claim is beta-carotene.

(4) The claim may indicate that it is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), Government Printing Office.

(5) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must 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, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between substances in diets low in fat and high in fruits and vegetables and cancer:

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.

[58 FR 2639, Jan. 6, 1993]

§ 101.79 Health claims: Folate and neural tube defects.

(a) *Relationship between folate and neural tube defects*—(1) *Definition.* Neural tube defects are serious birth defects of the brain or spinal cord that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

(2) *Relationship.* The available data show that diets adequate in folate may reduce the risk of neural tube defects. The strongest evidence for this relationship comes from an intervention study by the Medical Research Council of the United Kingdom that showed that women at risk of recurrence of a neural tube defect pregnancy who consumed a supplement containing 4 milligrams (mg)(4,000 micrograms (mcg)) folic acid daily before conception and continuing into early pregnancy had a reduced risk of having a child with a neural tube defect. (Products containing this level of folic acid are drugs). In addition, based on its review of a Hungarian intervention trial that reported periconceptional use of a multivitamin and multimineral preparation containing 800 mcg (0.8 mg) of folic acid, and its review of the observational studies that reported periconceptional use of multivitamins containing 0 to 1,000 mcg of folic acid, the Food and Drug Administration concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of neural tube defects.

(b) *Significance of folate*—(1) *Public health concern.* Neural tube defects occur in approximately 0.6 of 1,000 live births in the United States (i.e., approximately 6 of 10,000 live births; about 2,500 cases among 4 million live births annually). Neural tube defects are believed to be caused by many factors. The single greatest risk factor for a neural tube defect-affected pregnancy is a personal or family history of a pregnancy affected with a such a defect. However, about 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. The available evidence shows that diets adequate in folate may reduce the risk of neural tube defects but not of other birth defects.

(2) *Populations at risk.* Prevalence rates for neural tube defects have been reported to vary with a wide range of factors including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health, including maternal age and reproductive history. Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, those with insulin-dependent diabetes mellitus, and women with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics. Rates for neural tube defects vary within the United States, with lower rates observed on the west coast than on the east coast.

(3) *Those who may benefit.* Based on a synthesis of information from several studies, including those which used multivitamins containing folic acid at a daily dose level of ≥400 mcg (≥0.4 mg), the Public Health Service has inferred that folate alone at levels of 400 mcg (0.4 mg) per day may reduce the risk of neural tube defects. The protective effect found in studies of lower dose

folate measured by the reduction in neural tube defect incidence, ranges from none to substantial; a reasonable estimate of the expected reduction in the United States is 50 percent. It is expected that consumption of adequate folate will avert some, but not all, neural tube defects. The underlying causes of neural tube defects are not known. Thus, it is not known what proportion of neural tube defects will be averted by adequate folate consumption. From the available evidence, the Public Health Service estimates that there is the potential for averting 50 percent of cases that now occur (i.e., about 1,250 cases annually). However, until further research is done, no firm estimate of this proportion will be available.

(c) *Requirements.* The label or labeling of food may contain a folate/neural tube defect health claim provided that:

(1) *General requirements.* The health claim for a food meets all of the general requirements of §101.14 for health claims, except that a food may qualify to bear the health claim if it meets the definition of the term ''good source.''

(2) *Specific requirements*—(i) *Nature of the claim*—(A) *Relationship.* A health claim that women who are capable of becoming pregnant and who consume adequate amounts of folate daily during their childbearing years may reduce their risk of having a pregnancy affected by spina bifida or other neural tube defects may be made on the label or labeling of food provided that:

(B) *Specifying the nutrient.* In specifying the nutrient, the claim shall use the terms ''folate,'' ''folic acid,'' ''folacin,'' ''folate, a B vitamin,'' ''folic acid, a B vitamin,'' or ''folacin, a B vitamin.''

(C) *Specifying the condition.* In specifying the health- related condition, the claim shall identify the birth defects as ''neural tube defects,'' ''birth defects spina bifida or anencephaly,'' ''birth defects of the brain or spinal cord anencephaly or spina bifida,'' ''spina bifida and anencephaly, birth defects of the brain or spinal cord,'' ''birth defects of the brain or spinal cord;'' or ''brain or spinal cord birth defects.''

(D) *Multifactorial nature.* The claim shall not imply that folate intake is the only recognized risk factor for neural tube defects.

(E) *Reduction in risk.* The claim shall not attribute any specific degree of reduction in risk of neural tube defects from maintaining an adequate folate intake throughout the childbearing years. The claim shall state that some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folate during their childbearing years. Optional statements about population-based estimates of risk reduction may be made in accordance with paragraph (c)(3)(vi) of this section.

(F) *Safe upper limit of daily intake.* Claims on foods that contain more than 100 percent of the Daily Value (DV) (400 mcg) when labeled for use by adults and children 4 or more years of age, or 800 mcg when labeled for use by pregnant or lactating women) shall identify the safe upper limit of daily intake with respect to the DV. The safe upper limit of daily intake value of 1,000 mcg (1 mg) may be included in parentheses.

(G) The claim shall state that folate needs to be consumed as part of a healthful diet.

(ii) *Nature of the food*—(A) *Requirements.* The food shall meet or exceed the requirements for a ''good source'' of folate as defined in §101.54;

(B) *Dietary supplements.* Dietary supplements shall 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.

(iii) *Limitation.* The claim shall not be made on foods that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D per serving or per unit.

(iv) *Nutrition labeling.* The nutrition label shall include information about the amount of folate in the food. This information shall be declared after the declaration for iron if only the levels of vitamin A, vitamin C, calcium, and iron are provided, or in accordance with §101.9 (c)(8) and (c)(9) if other optional vitamins or minerals are declared.

(3) *Optional information*—(i) *Risk factors.* The claim may specifically identify risk factors for neural tube defects. Where such information is provided, it may consist of statements from §101.79(b)(1) or (b)(2) (e.g., Women at increased risk include those with a personal history of a neural tube defect-affected pregnancy, those with a close relative (i.e., sibling, niece, nephew) with a neural tube defect; those with insulin-dependent diabetes mellitus; those with seizure disorders who are being treated with valproic acid or carbamazepine) or from other parts of this paragraph (c)(3)(i).

(ii) *Relationship between folate and neural tube defects.* The claim may include statements from paragraphs (a) and (b) of this section that summarize the relationship between folate and neural tube defects and the significance of the relationship except for information specifically prohibited from the claim.

(iii) *Personal history of a neural tube defect-affected pregnancy.* The claim may state that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant. If such a statement is provided, the claim shall also state that all women should consult a health care provider when planning a pregnancy.

(iv) *Daily value.* The claim may identify 100 percent of the DV (100% DV; 400 mcg) for folate as the target intake goal.

(v) *Prevalence.* The claim may provide estimates, expressed on an annual basis, of the number of neural tube defect-affected births among live births in the United States. Current estimates are provided in §101.79(b)(1), and are approximately 6 of 10,000 live births annually (i.e., about 2,500 cases among 4 million live births annually). Data provided in §101.79(b)(1) shall be used, unless more current estimates from the U.S. Public Health Service are available, in which case the latter may be cited.

(vi) *Reduction in risk.* An estimate of the reduction in the number of neural tube defect-affected births that might occur in the United States if all women consumed adequate folate throughout their childbearing years may be included in the claim. Information contained in paragraph (b)(3) of this section may be used. If such an estimate (i.e., 50 percent) is provided, the estimate shall be accompanied by additional information that states that the estimate is population-based and that it does not reflect risk reduction that may be experienced by individual women.

(vii) *Diets adequate in folate.* The claim may identify diets adequate in folate by using phrases such as ''Sources of folate include fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.'' or ''Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables, legumes, whole grain products, fortified cereals, or dietary supplements.'' or ''Adequate amounts of folate can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables, legumes, whole grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement.''

(d) *Model health claims.* The following are examples of model health claims that may be used in food labeling to describe the relationship between folate and neural tube defects:

(1) *Examples 1 and 2.* Model health claims appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit (general population). The examples contain only the required elements:

(i) Healthful diets with adequate folate may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(ii) Adequate folate in healthful diets may reduce a woman's risk of having a child with a brain or spinal cord birth defect.

(2) *Example 3.* Model health claim appropriate for foods containing 100 percent or less of the DV for folate per serving or per unit. The example contains all required elements plus optional information: Women who consume healthful diets with adequate folate throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain or spinal cord. Sources of folate include

fruits, vegetables, whole grain products, fortified cereals, and dietary supplements.

(3) *Example 4.* Model health claim appropriate for foods intended for use by the general population and containing more than 100 percent of the DV of folate per serving or per unit: Women who consume healthful diets with adequate folate may reduce their risk of having a child with birth defects of the brain or spinal cord. Folate intake should not exceed 250% of the DV (1,000 mcg).

[61 FR 8779, Mar. 5, 1996; 61 FR 48529, Sept. 13, 1996, as amended at 65 FR 58918, Oct. 3, 2000]

§ 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.

(a) *Relationship between dietary carbohydrates and dental caries.* (1) Dental caries, or tooth decay, is a disease caused by many factors. Both environmental and genetic factors can affect the development of dental caries. Risk factors include tooth enamel crystal structure and mineral content, plaque quantity and quality, saliva quantity and quality, individual immune response, types and physical characteristics of foods consumed, eating behaviors, presence of acid producing oral bacteria, and cultural influences.

(2) The relationship between consumption of fermentable carbohydrates, i.e., dietary sugars and starches, and tooth decay is well established. Sucrose, also known as sugar, is one of the most, but not the only, cariogenic sugars in the diet. Bacteria found in the mouth are able to metabolize most dietary carbohydrates, producing acid and forming dental plaque. The more frequent and longer the exposure of teeth to dietary sugars and starches, the greater the risk for tooth decay.

(3) Dental caries continues to affect a large proportion of Americans. Although there has been a decline in the prevalence of dental caries among children in the United States, the disease remains widespread throughout the population, imposing a substantial burden on Americans. Recent Federal government dietary guidelines recommend that Americans choose diets that are moderate in sugars and avoid excessive snacking. Frequent between-meal snacks that are high in sugars and starches may be more harmful to teeth than eating such foods at meals and then brushing.

(4) Noncariogenic carbohydrate sweeteners, such as sugar alcohols, can be used to replace dietary sugars, such as sucrose and corn sweeteners, in foods such as chewing gums and certain confectioneries. Noncariogenic carbohydrate sweeteners are significantly less cariogenic than dietary sugars and other fermentable carbohydrates.

(b) *Significance of the relationship between noncariogenic carbohydrate sweeteners and dental caries.* Noncariogenic carbohydrate sweeteners do not promote dental caries. The noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section are slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and other fermentable carbohydrates and does not cause the loss of important minerals from tooth enamel.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met, except that noncariogenic carbohydrate sweetener-containing foods listed in paragraph (c)(2)(ii) of this section are exempt from § 101.14(e)(6).

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim relating noncariogenic carbohydrate sweeteners, compared to other carbohydrates, and the nonpromotion of dental caries may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim shall state that frequent between-meal consumption of foods high in sugars and starches can promote tooth decay.

(B) The claim shall state that the noncariogenic carbohydrate sweetener present in the food ''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.

(C) In specifying the nutrient, the claim shall state ''sugar alcohol,'' ''sugar alcohols,'' or the name or

names of the substances listed in paragraph (c)(2)(ii) of this section, e.g., ''sorbitol.'' D-tagatose may be identified as ''tagatose.''

(D) In specifying the disease, the claim uses the following terms: ''dental caries'' or ''tooth decay.''

(E) The claim shall not attribute any degree of the reduction in risk of dental caries to the use of the noncariogenic carbohydrate sweetener-containing food.

(F) The claim shall not imply that consuming noncariogenic carbohydrate sweetener-containing foods is the only recognized means of achieving a reduced risk of dental caries.

(G) Packages with less than 15 square inches of surface area available for labeling are exempt from paragraphs (A) and (C) of this section.

(H) When the substance that is the subject of the claim is a noncariogenic sugar, the claim shall identify the substance as a sugar that, unlike other sugars, does not promote the development of dental caries.

(ii) *Nature of the substance.* Eligible noncariogenic carbohydrate sweeteners are:

(A) The sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, and erythritol, or a combination of these.

(B) The sugars D-tagatose and isomaltulose.

(C) Sucralose.

(iii) *Nature of the food.* (A) The food shall meet the requirement in §101.60(c)(1)(i) with respect to sugars content, except that the food may contain D-tagatose or isomaltulose.

(B) A food whose labeling includes a health claim under this section shall contain one or more of the noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section.

(C) When carbohydrates other than those listed in paragraph (c)(2)(ii) of this section are present in the food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by the indwelling plaque pH test found in ''Identification of Low Caries Risk Dietary Components,'' dated 1983, by T. N. Imfeld, in Volume 11, *Monographs in Oral Science*, 1983. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from Karger AG Publishing Co., P.O. Box, Ch–4009 Basel, Switzerland, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Harvey W. Wiley Federal Building, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which describe the relationship between diets containing noncariogenic carbohydrate sweeteners and dental caries.

(2) The claim may indicate that development of dental caries depends on many factors and may identify one or more of the following risk factors for dental caries: Frequent consumption of fermentable carbohydrates, such as dietary sugars and starches; presence of oral bacteria capable of fermenting carbohydrates; length of time fermentable carbohydrates are in contact with the teeth; lack of exposure to fluoride; individual susceptibility; socioeconomic and cultural factors; and characteristics of tooth enamel, saliva, and plaque.

(3) The claim may indicate that oral hygiene and proper dental care may help to reduce the risk of dental disease.

(4) The claim may indicate that a substance listed in paragraph (c)(2)(ii) of this section serves as a sweetener.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between noncariogenic carbohydrate sweetener-containing foods and dental caries.

(1) Examples of the full claim:

(i) Frequent eating of foods high in sugars and starches as between-meal

snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.

(ii) 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.

(iii) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar used to sweeten this food, unlike other sugars, may reduce the risk of dental caries.

(iv) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar in [name of food], unlike other sugars, does not promote tooth decay.

(v) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay.

(2) Example of the shortened claim for small packages:

(i) Does not promote tooth decay.

(ii) May reduce the risk of tooth decay.

(iii) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar does not promote tooth decay.

(iv) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar may reduce the risk of tooth decay.

[61 FR 43446, Aug. 23, 1996, as amended at 62 FR 63655, Dec. 2, 1997; 66 FR 66742, Dec. 27, 2001; 67 FR 71470, Dec. 2, 2002; 71 FR 15563, Mar. 29, 2006; 72 FR 52789, Sept. 17, 2007]

§ 101.81 Health claims: Soluble fiber from certain foods and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fiber-containing fruits, vegetables, and grain products, such as whole oat products.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soluble fiber from certain foods to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories

from all fat. Recommended daily cholesterol intakes are 300 milligrams (mg) or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total- and LDL-cholesterol levels. Soluble fiber from certain foods, when included in a low saturated fat and cholesterol diet, also helps to lower blood total- and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in §101.14 shall be met. The label and labeling of foods containing psyllium husk shall be consistent with the provisions of §101.17(f).

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods ''may'' or ''might'' reduce the risk of heart disease.

(B) In specifying the disease, the claim uses the following terms: ''heart disease'' or ''coronary heart disease'';

(C) In specifying the substance, the claim uses the term ''soluble fiber'' qualified by the name of the eligible source of soluble fiber (provided in paragraph (c)(2)(ii)) of this section. Additionally, the claim may use the name of the food product that contains the eligible source of soluble fiber;

(D) In specifying the fat component, the claim uses the terms ''saturated fat'' and ''cholesterol'';

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section; and

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section is the only recognized means of achieving a reduced risk of CHD.

(G) The claim specifies the daily dietary intake of the soluble fiber source that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of soluble fiber sources listed in paragraph (c)(2)(ii) of this section that have been associated with reduced risk coronary heart disease are:

(*1*) 3 g or more per day of β-glucan soluble fiber from either whole oats or barley, or a combination of whole oats and barley.

(*2*) 7 g or more per day of soluble fiber from psyllium seed husk.

(ii) *Nature of the substance—Eligible sources of soluble fiber.* (A) Beta (β) glucan soluble fiber from the whole oat and barley sources listed below. β-glucan soluble fiber will be determined by method No. 992.28 from the ''Official Methods of Analysis of the AOAC INTERNATIONAL,'' 16th ed. (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*;

(*1*) *Oat bran.* Oat bran is produced by grinding clean oat groats or rolled oats and separating the resulting oat flour by suitable means into fractions such that the oat bran fraction is not more than 50 percent of the original starting material and provides at least 5.5 percent (dry weight basis (dwb)) β-glucan soluble fiber and a total dietary fiber content of 16 percent (dwb), and such that at least one-third of the total dietary fiber is soluble fiber;

(*2*) *Rolled oats.* Rolled oats, also known as oatmeal, produced from 100 percent dehulled, clean oat groats by steaming, cutting, rolling, and flaking, and provides at least 4 percent (dwb) of

β-glucan soluble fiber and a total dietary fiber content of at least 10 percent.

(*3*) *Whole oat flour*. Whole oat flour is produced from 100 percent dehulled, clean oat groats by steaming and grinding, such that there is no significant loss of oat bran in the final product, and provides at least 4 percent (dwb) of β-glucan soluble fiber and a total dietary fiber content of at least 10 percent (dwb).

(*4*) *Oatrim*. The soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour, also known as oatrim. Oatrim is produced from either oat bran as defined in paragraph (c)(2)(ii)(A)(*1*) of this section or whole oat flour as defined in paragraph (c)(2)(ii)(A)(*3*) of this section by solubilization of the starch in the starting material with an alpha-amylase hydrolysis process, and then removal by centrifugation of the insoluble components consisting of a high portion of protein, lipid, insoluble dietary fiber, and the majority of the flavor and color components of the starting material. Oatrim shall have a beta-glucan soluble fiber content up to 10 percent (dwb) and not less than that of the starting material (dwb).

(*5*) *Whole grain barley and dry milled barley*. Dehulled and hull-less whole grain barley with a β-glucan soluble fiber content of at least 4 percent (dwb) and a total dietary fiber content of at least 10 percent (dwb). Dry milled barley grain products include barley bran, barley flakes, barley grits, pearl barley, barley flour, barley meal, and sieved barley meal that are produced from clean, sound dehulled or hull-less barley grain using standard dry milling techniques, which may include steaming or tempering, and that contain at least 4 percent (dwb) of β-glucan soluble fiber and at least 8 percent (dwb) of total dietary fiber, except barley bran and sieved barley meal for which the minimum β-glucan soluble fiber content is 5.5 percent (dwb) and minimum total dietary fiber content is 15 percent (dwb). Dehulled barley, hull-less barley, barley bran, barley flakes, barley grits, pearl barley, and barley flour are as defined in the Barley Glossary (AACC Method 55–99), published in Approved Methods of the American Association of Cereal Chemists, 10th ed. (2000), pp. 1 and 2, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Association of Cereal Chemists, Inc., 3340 Pilot Knob Rd., St. Paul, Minnesota, 55121, or may be examined at the Center for Food Safety and Applied Nutrition Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Barley meal is unsifted, ground barley grain not subjected to any processing to separate the bran, germ, and endosperm. Sieved barley meal is an endosperm cell wall-enriched fraction of ground barley separated from meal by sieving or by air classification.

(*6*) *Barley betafiber*. Barley betafiber is the ethanol precipitated soluble fraction of cellulase and alpha-amylase hydrolyzed whole grain barley. Barley betafiber is produced by hydrolysis of whole grain barley flour, as defined in paragraph (c)(2)(ii)(A)(*5*) of this section, with a cellulase and alpha-amylase enzyme preparation, to produce a clear aqueous extract that contains mainly partially hydrolyzed beta-glucan and substantially hydrolyzed starch. The soluble, partially hydrolyzed beta-glucan is separated from the insoluble material by centrifugation, and after removal of the insoluble material, the partially hydrolyzed beta-glucan soluble fiber is separated from the other soluble compounds by precipitation with ethanol. The product is then dried, milled and sifted. Barley betafiber shall have a beta-glucan soluble fiber content of at least 70 percent on a dry weight basis.

(B)(*1*) Psyllium husk from the dried seed coat (epidermis) of the seed of *Plantago* (*P.*) ovata, known as blond psyllium or Indian psyllium, *P. indica,* or *P. psyllium*. To qualify for this claim, psyllium seed husk, also known as psyllium husk, shall have a purity of no less than 95 percent, such that it contains 3 percent or less protein, 4.5

percent or less of light extraneous matter, and 0.5 percent or less of heavy extraneous matter, but in no case may the combined extraneous matter exceed 4.9 percent, as determined by U.S. Pharmacopeia (USP) methods described in USP's ''The National Formulary,'' USP 23, NF 18, p. 1341, (1995), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*;

(*2*) FDA will determine the amount of soluble fiber that is provided by psyllium husk by using a modification of the Association of Official Analytical Chemists' International (AOAC's) method for soluble dietary fiber (991.43) described by Lee et al., ''Determination of Soluble and Insoluble Dietary Fiber in Psyllium-containing Cereal Products,'' *Journal of the AOAC International*, 78 (No. 3):724–729, 1995, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740 or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*;

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall include:

(*1*) One or more of the whole oat or barley foods from paragraphs (c)(2)(ii)(A)(*1*), (*2*), (*3*), and (*5*) of this section, and the whole oat or barley foods shall contain at least 0.75 gram (g) of soluble fiber per reference amount customarily consumed of the food product; or

(*2*) The food containing the oatrim from paragraph (c)(2)(ii)(A)(*4*) of this section or the barley betafiber from paragraph (c)(2)(ii)(A)(*6*) of this section shall contain at least 0.75 g of beta-glucan soluble fiber per reference amount customarily consumed of the food product; or

(*3*) Psyllium husk that complies with paragraph (c)(2)(ii)(B) of this section, and the psyllium food shall contain at least 1.7 g of soluble fiber per reference amount customarily consumed of the food product;

(B) The amount of soluble fiber shall be declared in the nutrition label, consistent with §101.9(c)(6)(i)(A).

(C) The food shall meet the nutrient content requirement in §101.62 for a ''low saturated fat'' and ''low cholesterol'' food; and

(D) The food shall meet the nutrient content requirement in §101.62(b)(2) for a ''low fat'' food, unless the food exceeds this requirement due to fat content derived from whole oat sources listed in paragraph (c)(2)(ii)(A) of this section.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soluble fiber from the eligible food sources from paragraph (c)(2)(ii) of this section and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total- and LDL-cholesterol;''

(3) The claim may include information from paragraphs (a) and (b) of this

section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soluble fiber from certain foods and coronary heart disease and the significance of the relationship;

(4) The claim may specify the name of the eligible soluble fiber;

(5) The claim may state that a diet low in saturated fat and cholesterol that includes soluble fiber from whole oats or barley is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of 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; 66 FR 66742, Dec. 27, 2001; 67 FR 61782, Oct. 2, 2002; 68 FR 15355, Mar. 31, 2003; 70 FR 40880, July 15, 2005; 70 FR 76162, Dec. 23, 2005; 73 FR 9947, Feb. 25, 2008; 73 FR 23953, May 1, 2008]

§ 101.82 Health claims: Soy protein and risk of coronary heart disease (CHD).

(a) *Relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. CHD is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL)-cholesterol levels are associated with increased risk of developing CHD. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk total cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL-cholesterol and, thus, with increased risk of CHD.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL-cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in plant foods that contain dietary fiber and other components.

(3) Scientific evidence demonstrates that diets low in saturated fat and cholesterol may reduce the risk of CHD. Other evidence demonstrates that the addition of soy protein to a diet that is low in saturated fat and cholesterol may also help to reduce the risk of CHD.

(b) *Significance of the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL-cholesterol are major modifiable risk factors in the development of CHD.

(2) Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL-cholesterol levels. Soy protein, when included in a low saturated fat and cholesterol diet, also helps to lower blood total and LDL-cholesterol levels.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that are low in saturated fat and cholesterol and that include soy protein with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that diets that are low in saturated fat and cholesterol and that include soy protein ''may'' or ''might'' reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: ''heart disease'' or ''coronary heart disease'';

(C) In specifying the substance, the claim uses the term ''soy protein'';

(D) In specifying the fat component, the claim uses the terms ''saturated fat'' and ''cholesterol'';

(E) The claim does not attribute any degree of risk reduction for CHD to diets that are low in saturated fat and cholesterol and that include soy protein;

(F) The claim does not imply that consumption of diets that are low in saturated fat and cholesterol and that include soy protein is the only recognized means of achieving a reduced risk of CHD; and

(G) The claim specifies the daily dietary intake of soy protein that is necessary to reduce the risk of coronary heart disease and the contribution one serving of the product makes to the specified daily dietary intake level. The daily dietary intake level of soy protein that has been associated with reduced risk of coronary heart disease is 25 grams (g) or more per day of soy protein.

(ii) *Nature of the substance.* (A) Soy protein from the legume seed Glycine max.

(B) FDA will assess qualifying levels of soy protein in the following fashion: FDA will measure total protein content by the appropriate method of analysis given in the ''Official Methods of Analysis of the AOAC International,'' as described at § 101.9(c)(7). For products that contain no sources of protein other than soy, FDA will consider the amount of soy protein as equivalent to the total protein content. For products that contain a source or sources of protein in addition to soy, FDA will, using the measurement of total protein content, calculate the soy protein content based on the ratio of soy protein ingredients to total protein ingredients in the product. FDA will base its calculation on information identified and supplied by manufacturers, such as nutrient data bases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein. Manufacturers must maintain records sufficient to substantiate the claim for as long as the products are marketed and provide these records, on written request, to appropriate regulatory officials.

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall contain at least 6.25 g of soy protein per reference amount customarily consumed of the food product;

(B) The food shall meet the nutrient content requirements in §101.62 for a ''low saturated fat'' and ''low cholesterol'' food; and

(C) The food shall meet the nutrient content requirement in §101.62 for a ''low fat'' food, unless it consists of or is derived from whole soybeans and contains no fat in addition to the fat inherently present in the whole soybeans it contains or from which it is derived.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL-cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease;

(2) The claim may state that the relationship between intake of diets that are low in saturated fat and cholesterol and that include soy protein and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total and LDL-cholesterol'';

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that are low in saturated fat and cholesterol and that include soy protein and CHD and the significance of the relationship;

(4) The claim may state that a diet low in saturated fat and cholesterol that includes soy protein is consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO);

(5) 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;

(6) 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 soy protein and reduced risk of heart disease:

(1) 25 grams of soy protein a day, 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 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.

[64 FR 57732, Oct. 26, 1999]

EFFECTIVE DATE NOTE: At 64 FR 57732, Oct. 26, 1999, §101.82 was added. Paragraph (c)(2)(ii)(B) contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§101.83 Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD).

(a) *Relationship between diets that include plant sterol/stanol esters and the risk of CHD.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease (CHD) is one of the most common and serious forms of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total cholesterol and low density lipoprotein (LDL) cholesterol

levels are associated with increased risk of developing coronary heart disease. High CHD rates occur among people with high total cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 millimole per liter (mmol/l)) or above and LDL cholesterol levels of 160 mg/dL (4.13 mmol/l) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/l) for total cholesterol, and 130 to 159 mg/dL (3.36 to 4.11 mmol/l) of LDL cholesterol.

(2) Populations with a low incidence of CHD tend to have relatively low blood total cholesterol and LDL cholesterol levels. These populations also tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in plant foods that contain dietary fiber and other components.

(3) Scientific evidence demonstrates that diets that include plant sterol/stanol esters may reduce the risk of CHD.

(b) *Significance of the relationship between diets that include plant sterol/stanol esters and the risk of CHD.* (1) CHD is a major public health concern in the United States. It accounts for more deaths than any other disease or group of diseases. Early management of risk factors for CHD is a major public health goal that can assist in reducing risk of CHD. High blood total and LDL cholesterol are major modifiable risk factors in the development of CHD.

(2) The scientific evidence establishes that including plant sterol/stanol esters in the diet helps to lower blood total and LDL cholesterol levels.

(c) *Requirements*—(1) *General.* All requirements set forth in § 101.14 shall be met, except § 101.14(a)(4) with respect to the disqualifying level for total fat per 50 grams (g) in dressings for salad and spreads and § 101.14(e)(6) with respect to dressings for salad.

(2) *Specific requirements*—(i) *Nature of the claim.* A health claim associating diets that include plant sterol/stanol esters with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(iii) of this section, provided that:

(A) The claim states that plant sterol/stanol esters should be consumed as part of a diet low in saturated fat and cholesterol;

(B) The claim states that diets that include plant sterol/stanol esters ''may'' or ''might'' reduce the risk of heart disease;

(C) In specifying the disease, the claim uses the following terms: ''heart disease'' or ''coronary heart disease'';

(D) In specifying the substance, the claim uses the term ''plant sterol esters'' or ''plant stanol esters,'' except that if the sole source of the plant sterols or stanols is vegetable oil, the claim may use the term ''vegetable oil sterol esters'' or ''vegetable oil stanol esters'';

(E) The claim does not attribute any degree of risk reduction for CHD to diets that include plant sterol/stanol esters;

(F) The claim does not imply that consumption of diets that include plant sterol/stanol esters is the only recognized means of achieving a reduced risk of CHD; and

(G) The claim specifies the daily dietary intake of plant sterol or stanol esters that is necessary to reduce the risk of CHD and the contribution one serving of the product makes to the specified daily dietary intake level. Daily dietary intake levels of plant sterol and stanol esters that have been associated with reduced risk of are:

(*1*) 1.3 g or more per day of plant sterol esters.

(*2*) 3.4 g or more per day of plant stanol esters.

(H) The claim specifies that the daily dietary intake of plant sterol or stanol esters should be consumed in two servings eaten at different times of the day with other foods.

(ii) *Nature of the substance*—(A) *Plant sterol esters.* (*1*) Plant sterol esters prepared by esterifying a mixture of plant sterols from edible oils with food-grade fatty acids. The plant sterol mixture shall contain at least 80 percent beta-sitosterol, campesterol, and stigmasterol (combined weight).

(*2*) FDA will measure plant sterol esters by the method entitled ''Determination of the Sterol Content in Margarines, Halvarines, Dressings, Fat Blends and Sterol Fatty Acid Ester

Concentrates by Capillary Gas Chromatography,'' developed by Unilever United States, Inc., dated February 1, 2000. The method, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, may be obtained from the Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Nutrition Science and Policy, 5100 Paint Branch Pkwy., College Park, MD 20740, and may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(B) *Plant stanol esters.* (*1*) Plant stanol esters prepared by esterifying a mixture of plant stanols derived from edible oils or byproducts of the kraft paper pulping process with food-grade fatty acids. The plant stanol mixture shall contain at least 80 percent sitostanol and campestanol (combined weight).

(*2*) FDA will measure plant stanol esters by the following methods developed by McNeil Consumer Heathcare dated February 15, 2000: ''Determination of Stanols and Sterols in Benecol Tub Spread''; ''Determination of Stanols and Sterols in Benecol Dressing''; ''Determination of Stanols and Sterols in Benecol Snack Bars''; or ''Determination of Stanols and Sterols in Benecol Softgels.'' These methods are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling, and Dietary Supplements, Division of Nutrition Science and Policy, 5100 Paint Branch Pkwy., College Park, MD 20740, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, and at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.*

(iii) *Nature of the food eligible to bear the claim.* (A) The food product shall contain:

(*1*) At least 0.65 g of plant sterol esters that comply with paragraph (c)(2)(ii)(A)(*1*) of this section per reference amount customarily consumed of the food products eligible to bear the health claim, specifically spreads and dressings for salad, or

(*2*) At least 1.7 g of plant stanol esters that comply with paragraph (c)(2)(ii)(B)(*1*) of this section per reference amount customarily consumed of the food products eligible to bear the health claim, specifically spreads, dressings for salad, snack bars, and dietary supplements in softgel form.

(B) The food shall meet the nutrient content requirements in §101.62 for a ''low saturated fat'' and ''low cholesterol'' food; and

(C) The food must meet the limit for total fat in §101.14(a)(4), except that spreads and dressings for salad are not required to meet the limit for total fat per 50 g if the label of the food bears a disclosure statement that complies with §101.13(h); and

(D) The food must meet the minimum nutrient contribution requirement in §101.14(e)(6) unless it is a dressing for salad.

(d) *Optional information.* (1) The claim may state that the development of heart disease depends on many factors and may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of CHD; elevated blood total and LDL cholesterol; excess body weight; high blood pressure; cigarette smoking; diabetes; and physical inactivity. The claim may also provide additional information about the benefits of exercise and management of body weight to help lower the risk of heart disease.

(2) The claim may state that the relationship between intake of diets that include plant sterol/stanol esters and reduced risk of heart disease is through the intermediate link of ''blood cholesterol'' or ''blood total and LDL cholesterol.''

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that include plant sterol/stanol esters and the risk of CHD and the significance of the relationship.

(4) The claim may include information from the following paragraph on the relationship between saturated fat and cholesterol in the diet and the risk of CHD: The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL cholesterol and, thus, with increased risk of CHD. Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL cholesterol levels.

(5) The claim may state that diets that include plant sterol or stanol esters and are low in saturated fat and cholesterol are consistent with ''Nutrition and Your Health: Dietary Guidelines for Americans,'' U.S. Department of Agriculture (USDA) and Department of 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,'' U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that include plant sterol or stanol esters and reduced risk of heart disease:

(1) *For plant sterol esters:* (i) Foods containing at least 0.65 g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of vegetable oil sterol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 1.3 g of vegetable oil sterol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of vegetable oil sterol esters.

(2) *For plant stanol esters:* (i) Foods containing at least 1.7 g per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of plant stanol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 g of vegetable oil stanol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies _____grams of vegetable oil stanol esters.

[65 FR 54717, Sept. 8, 2000; 65 FR 70466, Nov. 24, 2000, as amended at 66 FR 66742, Dec. 27, 2001; 68 FR 15355, Mar. 31, 2003; 70 FR 41958, July 21, 2005]