§ 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 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.

(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”; and

(C) In specifying the substance, the claim uses the term “soy protein,” and

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

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

(a) Relationship between diets that in-
clude plant sterol/stanol esters and the
risk of CHD. (1) Cardiovascular disease
means diseases of the heart and cir-
culatory system. Coronary heart dis-
ease (CHD) is one of the most common
and serious forms of cardiovascular dis-
ease 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 dis-
ease. 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. Border-
line 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 choles-
terol 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 compo-
ments.

(b) The scientific evidence demonstrates
that diets that include plant sterol/
stanol esters may reduce the risk of
CHD.

(c) Requirements—(1) General. All re-
quirements 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 dis-
ease may be made on the label or label-
ing of a food described in paragraph
(c)(2)(iii) of this section, provided that:
(A) The claim states that plant ste-
rol/stanol esters should be consumed as
part of a diet low in saturated fat and
cholesterol;

(B) The claim states that diets that in-
clude plant sterol/stanol esters
"may" or "might" reduce the risk of
heart disease;