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