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3. Minimum Nutrient Contribution Requirement

The plant sterol ester and plant stanol ester petitioners requested an exception for certain food products containing plant sterol/stanol esters from the minimum nutrient contribution requirement in the general health claim regulations (§101.14(e)(6)). The plant sterol ester petitioner requested an exception for dressings for salad, and the plant stanol ester petitioner requested a general exception for all foods. Section 101.14(e)(6) specifies that conventional foods bearing a health claim must contain 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrient addition, except as otherwise provided in individual regulations authorizing particular health claims. Dietary supplements are not subject to this requirement. As explained in the 1993 health claims final rule (58 FR 2478), FDA concluded that such a requirement is necessary to ensure that the value of health claims will not be trivialized or compromised by their use on foods of little or no nutritional value (58 FR 2478 at 2521). FDA adopted this requirement in response to Congress' intent that health claims be used to help Americans maintain a balanced and healthful diet (Ref. 105) (58 FR 2478 at 2489 and 2521).

The agency concludes that, with respect to dressings for salad, the minimum nutrient content requirements of §101.14(e)(6), while important, are outweighed by the public health importance of communicating the cholesterol-lowering benefits from consumption of plant sterol/stanol esters. The agency believes that the value of health claims will not be trivialized or compromised by their use on dressings for salad because dressings for salad often are consumed with foods rich in nutrients and fiber. Salads, for example, are usually rich in vegetables that provide important nutrients at significant levels, e.g., tomatoes—vitamins A and C; carrots—vitamin A; spinach—vitamin A and calcium.

In recognition of the usefulness of plant sterol/stanol esters in reducing blood cholesterol and the nutritional value of salad, FDA has determined that there is sufficient public health evidence to support providing an exception from §101.14(e)(6) for plant sterol/stanol ester-containing dressings for salad. However, the agency has decided not to grant the plant stanol ester petitioner's request for a general

exception from the minimum nutrient content requirement. The basis for the plant stanol ester petitioner's request for such an exception is that the cholesterol-lowering benefits of plant stanol ester-containing foods do not depend upon the presence of 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber. The agency, however, concludes that this rationale is not sufficient to justify an exception for all possible foods that would require an exception from the minimum nutrient contribution requirement in order to use the health claim. FDA believes that case-by-case consideration of the justification for an exception is necessary to ensure that the goals of the minimum nutrient contribution requirement are not undermined.

Accordingly, in §101.83(c)(2)(iii)(D), the agency is providing that dressings for salad bearing the health claim are excepted from the minimum nutrient requirement of §101.14(e)(6), but that other foods must comply with this requirement to be eligible to bear a health claim about plant sterol/stanol esters and the risk of CHD. The agency is requesting comment on this decision.

Manufacturers of foods that do not meet the minimum nutrient contribution requirement may submit comments with supporting information or petition the agency to request an exception from this requirement if they wish to use the health claim that is the subject of this interim final rule.

E. Optional Information

FDA is providing in §101.83(d)(1) that the claim may state that the development of heart disease depends on many factors and, consistent with other authorized CHD health claims, may list the risk factors for heart disease. The risk factors are those currently listed in §§101.75(d)(1), 101.77(d)(1), 101.81(d)(1), and 101.82(d)(1). 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.

In §101.83(d)(2), consistent with §§101.75(d)(2), 101.77(d)(2), 101.81(d)(2), and 101.82(d)(2), FDA is providing that the claim may state that the relationship between diets that include plant sterol/stanol esters and reduced risk of heart disease is through the intermediate link of "blood cholesterol" or "blood total cholesterol" and "LDL cholesterol." The relationship between plant sterol/stanol esters and reduced blood total cholesterol and LDL cholesterol is supported by the scientific

evidence summarized in this interim final rule.

In §101.83(d)(3), the agency is providing that, consistent with §§101.75(d)(3), 101.77(d)(3), 101.81(d)(3), and 101.82(d)(3), the claim may include information from §101.83(a) and (b). These paragraphs summarize information about the relationship between diets that include plant sterol/stanol esters and the risk of CHD and about the significance of that relationship. This information helps to convey the seriousness of CHD and the role that a diet that includes plant sterol/stanol esters can play to help reduce the risk of CHD.

In §101.83(d)(4), the agency is providing that the claim may include information on the relationship between saturated fat and cholesterol in the diet and the risk of CHD. This information helps to convey the importance of keeping saturated fat and cholesterol intake low to reduce the risk of CHD.

In §101.83(d)(5), the agency is providing that the claim may state that diets that include plant sterol/stanol esters and are low in saturated fat and cholesterol are part of a dietary pattern that is consistent with current dietary guidelines for Americans.

In §101.83(d)(6), the agency is providing that 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.

In §101.83(d)(7), the agency is providing that 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, 2000," USDA and Department of Health and Human Services (DHHS), Government Printing Office (GPO) (Ref. 103).

The optional information provided in §101.83(d)(4) through (d)(7) is consistent with optional information set forth in §§101.75, 101.77, 101.81, and 101.82. The intent of this information is to help consumers understand the seriousness of CHD in the United States and the role of diets that include plant sterol/stanol esters and are low in saturated fat and cholesterol in reducing the risk of CHD.