

U. S. Department of Health and Human Services
U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements
February 14, 2003

FDA Letter Regarding Enforcement Discretion With Respect to Expanded Use of an Interim Health Claim Rule About Plant Sterol/Stanol Esters and Reduced Risk of Coronary Heart Disease

Fred L. Shinnick, Ph.D.
Manager, Regulatory and Scientific Affairs
Cargill Health & Food Technologies
15407 McGinty Road W. MS110
Wayzata, Minnesota 55391

Dear Dr. Shinnick:

This letter is in response to your letter, dated January 6, 2003, requesting that FDA issue a letter stating its intention not to enforce certain requirements in the interim final rule (IFR) authorizing a health claim for plant sterol/stanol esters and reduced risk of coronary heart disease (CHD) (21 CFR 101.83). Citing new scientific evidence and comments submitted to FDA in the plant sterol/stanol esters health claim rulemaking, you requested that FDA exercise enforcement discretion until such time as a final rule is issued that extends the authorized health claim to all the forms and sources of phytosterols,⁽¹⁾ and product forms, that may effectively reduce blood cholesterol levels. You stated that the scientific literature now supports expanding the health claim to free forms of plant sterols and stanols; and to a wider range of products, including low-fat products. You further stated that current science shows that the lowest effective daily intake of free phytosterols is 800 mg/day with the minimum addition of 400 mg free phytosterols per serving, and that the phytosterol substance should consist of at least 80 percent sitosterol, campesterol, stigmasterol, sitostanol, and campestanol (combined weight).

In response to two health claim petitions, FDA published the IFR (65 FR 54686, September 8, 2000), which authorized the use, on food labels and in food labeling, of health claims on the relationship between plant sterol/stanol esters and reduced risk of CHD, pending consideration of public comment and publication of a final regulation. The IFR authorizes the use of a health claim relating plant sterol/stanol esters and reduced risk of CHD on labeling of (1) spreads and dressings for salad containing at least 0.65 g plant sterol esters per serving, and of (2) spreads, dressings for salad, snack bars, and dietary supplements in softgel form containing at least 1.7 g plant stanol esters per serving. Specific eligibility requirements for the use of the claim are listed in §101.83(c).

We received many comments in response to the IFR and to a notice reopening the comment period (66 FR 50825; October 5, 2001). These comments have brought to FDA's attention substantial additional scientific evidence regarding the cholesterol-lowering efficacy of phytosterols that has been published in peer-reviewed scientific journals since issuance of the IFR. The IFR authorized a health claim for only plant sterol esters and plant stanol esters, the substances that were the subjects of the two health claim petitions. Comments and supporting scientific evidence now suggest that currently available scientific support extends to a broader range of phytosterol substances. As you pointed out in your letter, FDA has received notifications regarding Generally Recognized as Safe (GRAS) determinations for various phytosterols used as food ingredients at levels necessary to justify the health claim. The agency has not objected to these notifications.

Publication of the phytosterol health claim final rule is an "A List" priority in CFSAN's FY 2003 Program Priorities. Pending completion of the final rule, FDA believes that it would be appropriate to consider the exercise of enforcement discretion with regard to use of the health claim on a wider range of foods.

Based on preliminary review of the comments and additional scientific evidence, FDA intends to consider the exercise of enforcement discretion, pending publication of the final rule, with respect to certain requirements of the health claim. The agency will consider exercising enforcement discretion with regard to the use of a claim about reduced risk of CHD in the labeling of a phytosterol-containing food,⁽²⁾ including foods other than those specified in §101.83(c)(2)(iii)(A), if: (1) the food contains at least 400 mg per reference amount customarily consumed (RACC) of phytosterols; (2) mixtures of phytosterol substances (i.e., mixtures of sterols and stanols) contain at least 80 percent beta-sitosterol, campesterol, stigmasterol, sitostanol, and campestanol (combined weight); (3) the food meets the requirements of §101.83(c)(2)(iii)(B)-(D); (4) products containing phytosterols, including mixtures of sterols and stanols or free forms, use a collective term in lieu of the terms required by §101.83(c)(2)(i)(D) in the health claim to describe the substance (e.g., "plant sterols" or "phytosterol"); (5) the claim specifies that the daily dietary intake of phytosterols that may reduce the risk of CHD is 800 milligrams (mg) or more per day, expressed as the weight of free phytosterol; (6) vegetable oils for home use that exceed the total fat disqualifying level bear the health claim along with a disclosure statement that complies with §101.13(h); and (7) the use of the claim otherwise complies with §101.83.

FDA is developing a final rule on this health claim and intends to publish it as expeditiously as possible. The agency cautions manufacturers that the final rule may differ from the broadened criteria listed above and that manufacturers would then be required to change their labels to conform to the final rule.

In the interim (i.e., before publication of the final rule), the agency intends to develop and promptly issue guidance that will contain FDA's enforcement discretion criteria for health claims for phytosterols and reduced risk of CHD. In issuing this guidance, FDA will adhere to the Agency's Good Guidance Practices (GGPs), 21 CFR 10.115.

Sincerely,

Christine L. Taylor, Ph.D.
Director
Office of Nutritional Products, Labeling and
Dietary Supplements
Center for Food Safety and Applied Nutrition

Footnotes:

1. The term "phytosterols" is used as a collective term for plant sterols, and their hydrogenated stanol forms, whether used in the free sterol form or esterified with fatty acids. Phytosterol is a term commonly used by manufacturers and distributors of these substances.
 2. The term "food" includes dietary supplements. See 21 U.S.C. 321(ff) (last sentence).
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Food Labeling: Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease; Interim Final Rule Federal Register, September 8, 2000

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