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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD, 20852

Re: FDA letter of February 14, 2003 re: health claims for phytosterols; request for reconsideration and comments on guidance that FDA is developing.
Docket Nos. 00P-1275 and 00P-1276: Comments, and request to reopen the comment period.

To Whom It May Concern:

I am writing with respect to a comment submitted to the Food and Drug Administration by Unilever Bestfoods North America. In that comment, Unilever Bestfoods explains why unesterified plant sterols or stanols (free phytosterols) should not at this time be eligible to be labeled with a health claim about the relationship between phytosterols and coronary heart disease (CHD) when formulated in "low-fat" or "fat-free" foods. As the company explains, these types of foods should be permitted to bear this health claim only if additional data are generated to establish that free phytosterols consistently result in meaningful levels of blood cholesterol reduction when incorporated in such foods. Based on my review of Unilever Bestfoods' comment and the data and information that support it, I conclude that this comment is correct.

As background information, my professional experience is in the field of lipid nutrition; in the past 6 years I have focused on the lipid-lowering effect of plant sterols and stanols. My team has been conducting numerous clinical trials involving the plant-derived supplement. Our papers in animals and humans have been cited in the 2000 FDA interim final ruling for a health claim for plant sterol and stanol esters in the USA. I co-chaired an international consensus summit on plant sterols in Stresa, Italy (March, 2001) and I am also co-editing the resulting position statement with other leaders in the field. Our work has also been cited in promotional material to support use and distribution of plant sterol esters in Canada (see www.plantsterols.ca). Based on my professional experience, I am familiar with scientific standards for reviewing studies of cholesterol-reducing

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agents and with views on this topic held by others in the scientific and medical community. I am also familiar with scientific standards for the approval of health claims for use in food labeling.

In an earlier letter to FDA (November 21, 2001), I expressed my opinion that free phytosterols as well as the esterified forms of these materials should be eligible for the use of the health claim about the role of phytosterols in reducing the risk of CHD. My comment was a general one, relating to the effect of phytosterols when formulated in the types of foods that had been conclusively studied at that time. With respect to the effect of phytosterols in low-fat or fat-free foods, however, the published studies are inconclusive. Based on my review of the data, I believe that it is not, at this time, possible to conclude that free phytosterols consistently result in meaningful levels of cholesterol reduction when formulated in low-fat or fat-free foods or beverages. I have provided a more detailed discussion on this topic in a recent review (St-Onge M-P and Jones PJH, Lipids (2003) 38: 367-375). As indicated by Unilever Bestfoods, the study by our team (St-Onge et al., 2003) as well as the study published by Denke (1995) demonstrate a lack of efficacy of free phytosterols, whereas the study by Nestel et al. (2003) suggests that free phytosterols in low-fat foods are less effective than esterified sterols.

Other published studies include the paper by Berger et al. (Pouteau E and Berger A, Eur J Nutr (2003) 42: 154-164). In this study, it was shown that un-esterified plant sterols significantly inhibited the absorption of cholesterol in mildly hypercholesterolemic men when given low-fat milk containing sterols. One of the key components of the study's success was based on the sterols being properly solubilized. This paper provides perfunctory evidence of the cholesterol-lowering capabilities of sterols, and with proper further substantiation from other studies, it can be ascertained whether it can be proven to be meaningful and consistent.

In summary, it is my opinion that the available scientific data do not at this time permit a conclusion to be drawn as to whether free phytosterols consistently and meaningfully reduce cholesterol levels when formulated in low-fat or fat-free foods. Further, I believe that, if others in my professional field were to consider the same data, they would reach a similar conclusion. For this reason, I support Unilever Bestfoods' submission to FDA which states that foods containing free phytosterols may be labeled with the health claim only if the foods are not "low-fat" or "fat-free," and that additional clinical data are needed in order to support a health claim about free phytosterols in "low-fat" or "fat-free" foods.

Sincerely yours,

Peter J. H. Jones, Ph.D.