



Nancy L. Schnell  
Deputy General Counsel - Marketing and Regulatory

3526 04 JUL 21 7:10

July 21, 2004

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

**Re: Docket Nos. 00P-1275 and 00P-1276  
Food Labeling: Health Claims; Plant Sterol/Stanol Esters  
Comments on letter submitted on behalf of GFA Brands, Inc.,  
dated June 2, 2004**

To Whom It May Concern:

On June 2, 2004, Hogan & Hartson, on behalf of GFA Brands, Inc. (GFA), submitted to the above-referenced docket a letter requesting that FDA permit a health claim for phytosterols and reduced risk of coronary heart disease (CHD) to be made on the labeling of conventional foods that are not low in saturated fat, provided that such foods contain a ratio of saturated fatty acids (SFA), monounsaturated fatty acids (MUFA), and polyunsaturated fatty acids (PUFA) of approximately 1:1:1. We write to oppose this request.

### ***SUMMARY***

If FDA were to grant GFA's request, foods that are relatively high in saturated fat could be eligible to be labeled with the phytosterol health claim, regardless of the CHD benefit provided by such foods. Rather than granting GFA's request, we recommend that FDA develop more specific science-based criteria for determining the appropriate saturated fat level in foods eligible for the phytosterol health claim. Such criteria should assure that the level of SFA in a food is reasonably related to the CHD benefit provided by the food while being as low as possible, consistent with current dietary guidelines.

### ***DISCUSSION***

In its letter, GFA states that, if total fat in the diet provides SFA, MUFA and PUFA in a ratio of about 1:1:1, there will be a beneficial effect on the ratio of low-density lipoprotein cholesterol (LDL) to high-density lipoprotein cholesterol (HDL). From this, GFA concludes that, if an individual food contains this same fatty acid ratio, it should be eligible to be labeled with the phytosterol health claim – regardless of its saturated fat content.

00P-1275

Unilever United States, Inc.  
700 Sylvan Avenue • Englewood Cliffs, NJ 07632  
Telephone (201) 894-2751 • Fax (201) 894-2727  
Nancy.Schnell@Unilever.com

C 28

Current dietary guidelines state that SFA increases the risk of coronary heart disease by raising blood cholesterol levels and recommend that Americans choose foods low in saturated fat.<sup>1</sup> The National Academy of Sciences (NAS) states that the level of saturated fat intake at which CHD risk begins to increase is very low and recommends that SFA consumption be “as low as possible while consuming a nutritionally adequate diet.”<sup>2</sup> Therefore, at this time, the most authoritative dietary guidance recommends the use of foods that are low in SFA for purposes of reducing the risk of CHD. Consistent with this guidance, FDA has, in general, required that foods bearing CHD-related health claims be low in saturated fat as defined by 21 CFR 101.62(c)(2) (see 21 CFR 101.75, 101.77, 101.81, 101.82, and 101.83).

In some cases, it may be appropriate to permit foods bearing a CHD health claim to contain more than a “low” level of SFA. In deciding on an appropriate saturated fat level, it is necessary to consider various criteria, including not only the ratio of SFA to PUFA and MUFA but also the anticipated CHD benefit from the food, other potentially beneficial substances in the food, and the total SFA and trans fat levels in the food.<sup>3</sup>

GFA’s request, however, recommends *only one* criterion, that is, that SFA, MUFA and PUFA must be present in a ratio of about 1:1:1. If FDA were to grant GFA’s request, foods that are relatively high in saturated fat could be eligible to be labeled with the phytosterol health claim, regardless of the CHD benefit provided by the foods. For example, a doughnut might be formulated with this fatty acid ratio and contain more than 4 g SFA per serving – a level that would exceed the disqualifying level in 21 CFR 101.14(a)(4).

Rather than granting GFA’s request, we recommend that FDA develop more specific science-based criteria for determining the appropriate saturated fat level in foods eligible for the phytosterol health claim. Such criteria should assure that the level of SFA in a food is reasonably related to the CHD benefit provided by the food, while being as low as possible, consistent with current dietary guidelines.

Respectfully submitted,



Nancy L. Schnell  
Deputy General Counsel –  
Marketing and Regulatory

---

<sup>1</sup> USDA, DHHS, Nutrition and Your Health: Dietary Guidelines for Americans (2000).

<sup>2</sup> NAS, Institute of Medicine, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (2002), p. S-4.

<sup>3</sup> See e.g., FDA letter re walnuts and CHD (March 9, 2004) (Docket No. 02P-0292).