



Unilever

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July 19, 2004

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

**Re: Docket No. 2003Q-0401
Qualified Health Claim (QHC) Omega-3 Fatty Acids and Coronary
Heart Disease Health Claim
Comments on letter from GFA Brands, Inc. of May 14, 2004**

To Whom It May Concern:

On May 14, 2004, GFA Brands, Inc. (GFA) submitted to the above-referenced docket a letter requesting that FDA permit a qualified health claim for omega-3 fatty acids and 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; or alternatively, have a saturated fat content that does not exceed one-third of total fat. 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 omega-3 qualified 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 omega-3 qualified 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 omega-3 qualified health claim – regardless of its saturated fat content.

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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.¹ 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.”² 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.³

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 (or alternatively that SFA must not exceed one-third of total fat). If FDA were to grant GFA’s request, foods that are relatively high in saturated fat could be eligible to be labeled with the omega-3 qualified health claim, regardless of the CHD benefit provided by the foods. For example, a doughnut could 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 omega-3 qualified 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,



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

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

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