April 13, 2004

Dockets Management Branch (HFA-305)
Docket No. 2003N-0076
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom it May Concern:

My name is Dale E. Bauman and I am Liberty Hyde Bailey Professor in the Department of Animal Science at Cornell University. I am coauthoring this letter with Adam L. Lock, Post-Doctoral Research Fellow in my department. As members of the scientific community, we appreciate the opportunity to provide comment on trans fatty acids in nutrition labeling and we are writing to communicate scientific information about the health effects of naturally occurring trans fatty acids in the diet.

The majority (80-90%) of dietary trans fatty acids found in the U.S. diet originate from partially hydrogenated vegetable oils that are used in cooking and preparation of processed foods (1, 2). The remaining small percent are naturally occurring, coming from food products derived from ruminants (3, 4). The major trans fatty acid isomers found in ruminant meat and milk are 18 carbon monounsaturated fatty acids. Vaccenic acid (VA; trans-11 18:1) is the most common, accounting for 60-80% of the total (3,5). The second most common group of trans fatty acids in ruminant fat is conjugated linoleic acids with the cis-9, trans-11 isomer (CLA) being the major form representing 75-90% of total conjugated linoleic acids (6).

Unfortunately, little or no distinction is generally made between the biological effects of various trans fatty acid isomers. Although most of the available data examining variables associated with coronary heart disease relate to trans fatty acids from partially hydrogenated vegetable oils, these data have been broadly extrapolated to imply that high intake of any and all trans fatty acid isomers is associated with increased coronary heart disease. Whereas ruminant trans fat contains mainly VA, PHVO contains a Gaussian distribution of trans 18:1 isomers that centers on trans-9, trans-10, trans-11 and trans-12 (3, 4, 5). It is important to consider the significance of double bond positioning in trans fatty acids in terms of their biological effects. These structural differences relate to differences in metabolism and biological outcomes. For example, Hodgsen et al. (7) found that while the intake of trans-9 and
Trans-10 18:1 were positively correlated with heart disease, the intake of VA was not. We have shown that VA and CLA are both effective in reducing the risk of cancer in biomedical studies with animal models whether given as a chemically synthesized supplement or provided as a naturally enriched food component (butter) in the diet (8, 9, 10, 11).

A number of epidemiological studies have investigated the relationship between dietary intakes of trans fatty acids and coronary heart disease, and these are cited as strong evidence for the need to reduce the intake of trans fats (2, 5). Again, structural differences among trans fatty acid isomers may be an important consideration in regard to their effect on coronary heart disease. Some epidemiological studies have provided data that allow a comparison of food sources, and our assessment of these studies indicates that the positive relationship between trans fatty acids and coronary heart disease risk is specifically related to the intake of trans fatty acids derived from vegetable fats (12-16). In fact, in three of these studies (12, 14, 16) there was a negative association between the intake of trans fatty acids of animal origin and the risk of coronary heart disease. For example, Willet et al. (12) found that as the intake of trans fatty acids from vegetable fat progressively increased, the relative risk of coronary heart disease also increased with a risk of 1.78 at the highest quintile; in contrast, risk of coronary heart disease decreased with increasing intake of trans fatty acids from animal sources. Based on the results from these epidemiological studies, we conclude that trans fat from ruminant fats differ in their relationship to the risk of coronary heart disease and suggest that this difference relates to the type of trans fatty acids, specifically the presence of VA and CLA.

In addition, investigations with both animal and cell models have clearly established that CLA is anticarcinogenic for many types of cancer. These anticarcinogenic properties of CLA extend to VA because a significant amount of VA (~20%) is converted to CLA in humans, thereby increasing the CLA supply to tissues (17, 18). In collaboration with scientists at Roswell Park Cancer Institute, we demonstrated that dietary consumption of VA/CLA enriched butter was effective in reducing the incidence of tumors in a rat-model of mammary carcinogenesis (8, 10, 11). During our initial studies, we made the unexpected observation that the tissue concentration of CLA was greater when the CLA was supplied by butter than for a comparable amount of the same chemically prepared CLA isomer (8). Further studies showed that this difference was related to endogenous synthesis of CLA from the VA present in the dietary supply of butter. Fatty acid analysis showed that the conversion of dietary VA to CLA resulted in a dose-dependent increase in the accumulation of CLA in the mammary fat pad and this was accompanied by decreases in both tumor incidence and tumor number (10). Furthermore, we showed that the predominant mechanism for the anti-cancer effects of VA is related to its conversion to CLA via the enzyme \( \Delta^9 \)-desaturase (11). From these data, it is clear that both CLA and VA, the predominant trans fatty acids present in dairy and ruminant products, are anticarcinogenic.
Recent studies have shown that pure cis-9, trans-11 CLA provides protection against cholesterol-induced atherosclerosis in the rabbit model (19). Likewise, Toomey et al. (20) used Apo E(-/-) mice that had pre-established atherosclerosis and found that a dietary supplement of cis-9, trans-11 CLA not only retarded further development of atherosclerotic lesions, but also induced regression of the lesions in the aorta. We have recently extended these data using the hamster model of human lipoprotein metabolism and we found that feeding a VA/CLA-enriched butter increased tissue fatty acid concentrations of VA and CLA, resulting in significant reductions in total and LDL plasma cholesterol content and a reduction in the plasma LDL:HDL-cholesterol ratio, a common marker for risk of atherosclerosis (21, 22). Based on the typical relationship between VA and CLA in ruminant fat and the extent of conversion of VA to CLA in humans (17), Parodi (18) has suggested that multiplying the CLA intake from human diets by 1.4 provides an estimate of the effective physiological dose of CLA derived from ruminant products.

In summary, trans fatty acid isomers that occur naturally in beef and dairy foods are not harmful, and in fact there is growing evidence that they may be beneficial to health. For this reason, we believe that the naturally occurring trans fatty acids that occur in ruminant-derived food products should be exempt from trans fatty acid labeling. In Denmark, the Danish Veterinary and Food Administration has already recognized the critical distinction between man-made and naturally occurring trans fats and its orders specifically exempt naturally occurring the trans fatty acids that naturally occur in animal fats (5).

Thank you for your consideration.

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References:


