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January 17, 2001

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

Ref: Docket No. 94P-0036 **Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims.**

I am writing this note on behalf of the committee members of the W-181 Multi-state Project (Modifying Milk Fat Composition for Improved Manufacturing Qualities and Consumer Acceptability).

The members of this project expressed their concerns about labeling of trans fatty acids in a letter dated February 2, 2000 addressed to the Food and Drugs Administration (copy enclosed).

As mentioned earlier, the project had more than 30 members from 20 States plus collaborators from 5 countries. The members met again on January 8-9, 2001 at the University of Nevada, Reno and would like to reaffirm their concerns about labeling of trans fatty acids. Our main concerns are:

1. All trans fatty acids are not equal. Individual fatty acid isomers are metabolized differently and have unique biological effects.
2. Fatty acids with less than 12 carbons should not be included as saturated fat on food labels.
3. Trans fatty acids information should be on a separate line from saturates on food labels.

Please see the attached letter for details on these concerns.

Submitted:



Dr. Tilak R. Dhiman
Chairman, W-181 Multi-state Project Committee

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

January 16, 2001

Re: Docket No. 94P-0036 **Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims**

We, the members of the W-181 Multi-state Project (Modifying Milk Fat Composition for Improved Manufacturing Qualities and Consumer Acceptability), would like to make the following comments.

1) We recognize that the current state of the art does not allow routine differentiation of all the isomers of *trans* fatty acids (tFA), although it is possible for research purposes. Nevertheless, we want to go on the record and inform you that they may indeed have different and individual metabolic effects. In the future when these regulations are reviewed this is an area that will need to be examined.

We emphasize that all tFA are not equal. Individual fatty acid isomers are metabolized differently and have unique biological effects. The tFA present in dairy fat have been in the human diet for millennia. The more complex array and higher levels of *trans* isomers found in partially hydrogenated vegetable oils are recent additions to the human diet and have been present in large amounts only since the years following World War II. In unmodified milk fat the major isomer is *trans*-11 octadecenoic acid, (vaccenic acid). This isomer is capable of being desaturated by mammals to form the 9c, 11t-conjugated linoleic acid, (CLA) (Santora et al., 2000). This 9c, 11t- CLA has been identified to be protective for mammary cancer in a rodent model (Ip et al., 1999). Some other CLA isomers have different effects but can not be formed from *trans* monoenes by mammals. The *trans*-10-18:1 isomer is elevated during milk fat depression in cows (Grininari et al., 1998). Teter et al., using a mouse model, found that *trans*-9-18:1, (elaidic acid), but not vaccenic acid, lowered the milk fat (Teter et al., 1995). Additional studies are in progress. Obviously, all *trans* isomers are not the same. These studies show that individual tFA have unique metabolic and physiological effects and it may become desirable in the future to differentiate among various specific isomers.

2) **Fatty acids with less than 12 carbons should not be included as saturated fat on food labels.** We suggest that while the saturated fatty acid issue is open, that the regulation be altered to reflect the known physiology of saturated fatty acids. This recommendation is made based on the following concepts.

- a) Physiologically they are metabolized more like carbohydrate than fat. They are absorbed, but do not form chylomicrons, and are transported by the portal vein to the liver where they are oxidized for energy. (Vance and Vance, 1985; Gurr and Harwood, 1991; Kabara, 1999)

- b) The medium-chain saturated fatty acids (4:0 to 10:0) were not significantly associated with the risk of coronary heart disease in women (Hu, 1999).
- c) Butyric acid (4:0) has been shown to induce apoptosis in mammary cancer cells (Mandal, 1996) and to induce differentiation and interfere with signal transduction of ovarian carcinoma cells (Krupitza et al., 1996; Krupitza et al., 1995). Effects of butyric acid and other milk lipids have been reviewed by Parodi (1997).

3) Trans fatty acid information should be on a separate line from saturates on food labels. There are obvious chemical and metabolic differences between saturated fatty acids and *trans* fatty acids. *Trans* fatty acids are by definition unsaturated fatty acids. To group them with the saturates will mislead the public. The physiological differences are not trivial either. While certain saturated fatty acids tend to increase total cholesterol, they increase LDL-C less than they do the HDL-C. This leads to a more desirable ratio of LDL/HDL. The Harvard Nurses Study (Hu, 1999) found no relationship between consumption of animal fat and CHD. Diets rich in stearic acid did not increase thrombotic risk factors in males (Kelly et al., 1999) and replacement of partially hydrogenated soybean oil by palm oil in margarine raised the HDL-C but did not significantly change the total cholesterol or LP(a) although the numerical value for the palm diet was the lowest of all and the tFA diet value was the highest (Muller et al., 1998). Human studies show that feeding partially hydrogenated vegetable oils usually lower the HDL-C and increase the LDL-C, resulting in a less favorable ratio (Sampugna and Teter, 1996). Saturated fatty acids also tend to lower Lp(a), an independent risk factor for CHD, whereas, tFA tend to increase Lp(a). These are obviously two different classes of fatty acids. Considering these differences, tFA should appear on a separate line in the nutrient label.

The FDA raises the issue of an RDI for saturates and tFA. Since some will argue that the RDI for tFA should be zero, and other research shows that certain isomers of tFA may be beneficial (see section 1), we suggest, in the absence of conclusive data, that a RDI not be established at this time.

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