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March 21, 2000

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

RE: Proposed Rule – Trans Fatty Acid in Nutrition Labeling, Nutrient Content Claims and Health Claims (Docket 94P-0036)

Good Morning:

The FDA is concerned about coronary Heart Disease (CHD) that is caused from consumption of fatty acids in the American diet. A petitioner requested that FDA review Trans Fatty Acids (TFA) and proposed that FDA review these compounds in food.

1. FDA found that there is no universally standard test for TFA in cooked finished foods. (Federal Register Nov. 17, 1999 V64, Number 221 p. 62757) How accurate are the cited studies, and how can one compare results if different measurements of TFA are used and compared to the studies results? How accurate are labeling measurements going to be for measurements of finished foods?
2. The UK recommended 4.4 g/day TFA on a 2,000 calorie diet (Ibid. p 62753) In fact many Americans consume more than 2000 calories per day, and more grams of fats per day than assumed in the cited studies. The amounts of TFA consumed are proportional to UK considering the actual diet of actual calories and fats. TFA intake by the average American at 6.7 g/day for men and 6.8 g/day for women is appropriate considering US eating habits. (Ibid. p. 62752) (One can easily consume more than 1,000 calories (and significant fat) at a common fast food restaurant for a hamburger sandwich, fries and soft drink) The FDA further states that 30 percent of margarine products currently on the market have been reformulated to reduce TFA before any regulation. Thus, the intake of TFA by Americans will be lower than stated in this document. (Ibid. p. 62765) FDA has not considered that significant TFA consumption is outside FDA labeling control. (restaurants, bakeries, etc.)
3. Questions arise about how accurately the cited studies were able to measure TFA intake for their studies. (See statement 1 above.) It appears that the estimations for amount of fat and the estimations for calories are not the same. Are those who are consuming the mean TFA the same individuals consuming 2,455 kcal/day? (Ibid. p 62765) There does not seem to be objective evidence that use of means is appropriate in this situation. It would be more objective to determine the TFA for individuals at various caloric intakes. Is it possible that a number of individuals consuming large amounts of fats are consuming most of the TFA and the

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normal/average (greatest number of consumers) are in a safe or normal zone? The FDA should seek this scientific evidence before making any decision.

4. The FDA states that they do not want to confuse the public from “years of consumer education messages” about saturated fat: yet will confuse the public by mixing two different substances in the proposed labeling. FDA seems to knowingly want to miss-lead and miss-educate the public by combining two substances (TFA and Saturated Fats (SF)) that have different effects on LDL-C. (Ibid. 62755) TFAs are unsaturated fats.
5. The FDA errors in neglecting to indicate the effects of the obesity of the American consumer in CHD. FDA also neglects to mention the benefits of a proper regime of exercise in reducing CHD.
6. FDA is compelled by law not to misbrand products. Including TFA in the total SF is misbranding *de facto* by calling TFAs SF.
7. FDA states that the epidemiological association of TFA and CHD is imprecise and that no dose response relationship has been established. (Ibid. 62752) FDA fails to implicate fat intake and obesity in CHD. FDA fails to evaluate the current programs under FDA control that are intended to decrease CHD. Therefore it is difficult to see why FDA can state that this TFA regulation will prevent any CHD or show that this proposal will give any health benefit to the American consumer by labeling change.
8. FDA states from Table 2 (Ibid. 62767) that consumers will change their eating habits. FDA fails to take into account increased cholesterol consumption because of this ruling and total fat intake from reformulated products that consumers believe are more healthy. Many consumers consume more of “reduced” products thinking they are safe, and *de facto* increase the total caloric intake of the “reduced” constituent. This makes it difficult to believe the conclusions (Ibid. p. 62768) that FDA believes CHD will decrease. (FDA does not consider the possibility that CHD may increase because of scenarios not included in the document.)
9. FDA estimates that only about 1.8 percent of foods would be exempted. (Ibid. p 62787) FDA does not consider baked items (and other foods high in TFA) sold in restaurants, bakeries, and deli establishments that are major contributors to TFA in the American diet. (Both by calories and fats consumed.)

I would recommend that the FDA reconsider the proposed rule. I encourage FDA to use its power and authority to educate the public in changing current dietary habits to more healthy habits that reduce obesity and encourage exercise, both of which are known to improve the health of the public and decrease CHD.

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I would discourage FDA from pursuing the proposed labeling rule. TFAs are not saturated fats. Including some unsaturated fatty acids with SF is not based on fact, is misleading and is misbranding. This will add more confusion to consumers rather than being of assistance to consumers. Future knowledge of various health consequences may be more difficult to state on labels. Re-education of consumers to new scientific facts will be more difficult.

FDA has made bold assumptions that do not take into account other important health concerns. The relationship of CHD to exercise, total fat intake, and obesity for example were not considered. How much data is from people who are smokers? (Smoking is known to be a cause of CHD and was not mentioned.) These factors (disregarding both LDL and HDL) have major effects on long term health of the American public and must be considered in making any dietary changes. These facts skew the results cited in the document. Furthermore many Americans consume fats and TFA from sources not effected by this proposed rule. (Restaurants, bakeries, etc.) Therefore, I encourage the FDA to pursue better ways to change TFA in the American diet and decrease CHD than what has been proposed.

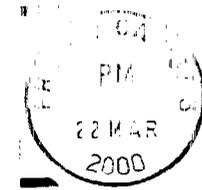
Respectfully,

A handwritten signature in cursive script that reads "Clifford M. Winger".

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