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October 7, 2003

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VIA MESSENGER

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

Re: Advanced Notice of Proposed Rulemaking – Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements, Docket No. 03N-0076

Dear Sir or Madam:

On behalf of the American Palm Oil Council (“APOC”), we thank FDA for this opportunity to respond to FDA’s advanced notice of proposed rulemaking “Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,” 68 Fed. Reg. 41507 et seq. (July 11, 2003). We urge FDA to require foods which contain a disclosable amount of *trans* fat to include a footnote to the Nutrition Facts label stating that, “Intake of *trans* fat should be kept low while maintaining a nutritionally adequate diet.”

Americans need to be better educated about *trans* fats, and encouraged to lessen consumption of *trans* fats. FDA found strong, consistent scientific evidence of a direct causal relationship between *trans* fat intake and the risk of cardiovascular heart disease.¹ Similarly, the *Dietary Guidelines 2000* advised that “[f]oods high in *trans* fatty acids tend to raise blood cholesterol,”² and the American Heart Association warned that “dietary *trans*-unsaturated fatty acids can increase LDL cholesterol and reduce HDL

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¹ *Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims*, 68 Fed. Reg. 41,433, 41,445 (July 11, 2003) (*Trans Fatty Acids in Nutrition Labeling*).

² U.S. Department of Agriculture and U.S. Department of Health and Human Services, *Nutrition and Your Health: Dietary Guidelines for Americans* (5th ed. 2000).

cholesterol."³ Drs. Walter Willett and Albert Ascherio, noted members of the Harvard University Department of Nutrition and Epidemiology, reviewed the growing science on *trans* fatty acids and heart disease, and concluded:⁴

Although the percentage of coronary heart disease deaths in the United States attributable to intake of *trans* fatty acids is uncertain, even the lower estimates from the effects on blood lipids would suggest that more than 30,000 deaths per year may be due to consumption of partially hydrogenated vegetable fat. Furthermore, the number of attributable cases of nonfatal coronary heart disease will be even larger.

In a recent interview, Dr. Willett also explained that hydrogenation eliminates omega-3 fatty acids, which are protective against heart disease and possibly other diseases.⁵

Trans fats differ chemically, functionally and physiologically from saturated fats. There is compelling evidence that *trans* fats pose even greater risks than saturated fats, by reducing protective HDL-cholesterol levels relative to saturated fats.⁶

FDA's review of the intervention trials showed that HDL-C decreased when *trans* fats replaced saturated fats. . . . Further, Federal Government advisory groups . . . and an advisory group of health professionals . . . have stated that substitution of *trans* fat for saturated fat lowers HDL-C. . . .

Drs. Willett and Ascherio concluded that *trans* fatty acids reduce protective HDL cholesterol, and also increase lipoprotein Lp(a), a potent indicator of cardiovascular risks.⁷

³ Ronald M. Krauss et al., *American Heart Association Dietary Guidelines, Revision 2000: A Statement for Healthcare Professionals From the Nutrition Committee of the American Heart Association*, 2296, 2300 (2000).

⁴ Walter Willett & Albert Ascherio, *Trans Fatty Acids: Are the Effects Only Marginal?*, 84 Am. J. Pub. Health 722 (1994) (Willett & Ascherio).

⁵ *Nutrition: Conversation with an expert*, Harvard Health Letter (Sept. 1, 2003).

⁶ *Trans Fatty Acids in Nutrition Labeling*, 68 Fed. Reg. at 41,448.

⁷ Willett & Ascherio, 84 Am. J. Pub. Health at 723.

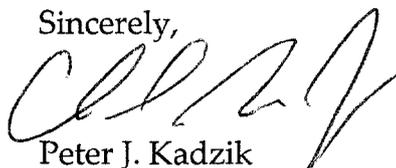
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The health risks posed by *trans* fats led FDA to require separate disclosure of *trans* fats on food labels. Consumers, however, will be left to wonder "why," unless food labels also alert them to the goal of low *trans* fat consumption. For over a decade, governmental and public health organizations have made intensive efforts to educate Americans about the danger of high levels of consumption of fats and saturated fats, and to urge Americans to reduce their dietary intake of fats and saturated fats. Public health initiatives regarding *trans* fats, however, have gained momentum in just the past few years. Consumers are just beginning to focus upon *trans* fats, and there remains a great deal of confusion and ignorance about *trans* fats. There is persuasive evidence that Americans use and rely upon nutrition labels to make better dietary choices. By requiring a footnote that specifically addresses *trans* fat consumption, FDA will help hasten the education of the American public. Furthermore, if food products which contain *trans* fats are required to state the goal of lessening *trans* fat consumption, then food manufacturers are less likely to use *trans* fats.

FDA also is considering alternatively-stated footnotes – e.g., a footnote that recommends low intake not just of *trans* fat, but also saturated fat and/or total fat. This alternative would be less beneficial to public health. It would weaken the relatively new focus upon *trans* fats, and confuse the important differences between *trans* and saturated fats. As we have noted, there is disturbing evidence that *trans* fats pose greater health risks than saturated fats. A footnote with a single clear message to lessen *trans* fat consumption more effectively promotes FDA's goal that "changes in food purchases by consumers and reformulation by producers in response to this rule will result in an overall decrease in *trans* fat intake in the U.S. population."⁸

Sincerely,



Peter J. Kadzik

Charles L. Miller Jr.

Doreen M. Langa

⁸ *Trans Fatty Acids in Nutrition Labeling*, 68 Fed. Reg. at 41468.