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1156 FIFTEENTH STREET N.W., SUITE 900 • WASHINGTON, D.C. 20005 • (202) 785-3232 • FAX (202) 223-9741  
E-MAIL: NAMM@kellencompany.com

October 9, 2003

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

RE: Docket No. 03N-0076 -- Food Labeling: Trans Fatty  
Acids in Nutrition Labeling; Consumer Research to  
Consider Nutrient Content and Health Claims and Possible  
Footnote or Disclosure Statements, 68 Fed. Reg., 41507

Dear Docket Manager:

The National Association of Margarine Manufacturers (NAMM) tried unsuccessfully, on October 9, 2003 to send our comment on the Advance Notice of Proposed Rulemaking (ANPR) because of problems on FDA's website. Please note the attached explanation of the problem that we encountered when trying to attach our comments on your website. Please accept this mailing of our comments, postmarked today instead.

Thank You,

*Richard E. Cristol*  
Richard E. Cristol  
President

03N-0076

C10



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Trans Fatty Acids in Nutrition Labeling; Consumer  
Research to Consider Nutrient Content and Health  
Claims and Possible Footnote or Disclosure  
Statements, 68 Fed. Reg., 41507

Dear Sir or Madam:

The National Association of Margarine Manufacturers (NAMM) respectfully requests FDA to reopen the comment period on the Advance Notice of Proposed Rulemaking (ANPR) on Trans Fat Labeling as referenced above, because of significant new and relevant information expected to be made publicly available in the next few months. We also wish to take this opportunity to comment on other issues raised in the ANPR.

For more than 65 years, NAMM has been the voice of the United States margarine industry. Although the margarine industry has led the way in making major reductions in the trans fat content of its products, it continues to have strong interest in providing appropriate information to consumers about trans fat. NAMM was among the very first food sectors to endorse quantitative labeling of trans fats and believes this information will help consumers make better dietary choices.

Comment Period Extension or Reopening of Comment Period Requested

NAMM has been tracking the progress of the FDA-sponsored, Dietary Reference Intake (DRI) study now being conducted by the Food and Nutrition Board, Institute of Medicine, National Academies. This study will "identify general guiding principles for use in setting reference values for nutrients on the food label". The study is expected to

set forth principles for determining label reference values and other guidance information for nutrients for which previous DRI assessments did not specify intake recommendations, like trans fat. We believe these principles and guidance will likely be significantly helpful to anyone commenting on the ANPR for trans fat in nutrition labeling as well as to FDA. It is our understanding that this report is likely to be made public later this year.

For these reasons, as well as the fact that FDA requested the DRI study for purposes such as determining how to label nutrients in the context of a healthful diet, NAMM encourages FDA to announce that it will reopen the comment period on this ANPR at the time the DRI is published by the National Academies. The Federal Regulatory Impact Analysis in the final rule on trans fat labeling noted any changes to labels for companies declaring trans fat will result in costs to the industry in excess of \$100 million dollars. Any further consideration of trans fat labeling should be made with all available information so that any additional changes to the label can be accomplished at one time.

### FDA's Consumer Research

Also, we understand that FDA is planning to go forward with consumer research to assess further labeling of trans fat, perhaps in the context of a footnote juxtaposed to the Nutrition Facts box or in the form of a nutrient content claim disclosure on the Principal Display Panel of the food label. As NAMM pointed out in its December 16, 2002 comments on FDA's November 15, 2002 proposed footnote on trans fat, we believe consumers, in general, overreact to footnotes on food labels relating to reduction or elimination of nutrients or ingredients that are framed in a negative way. As consumer research submitted to FDA by the International Food Information Council earlier this year demonstrated, unintended behavioral consequences often result from such overreaction.

Therefore, NAMM urges FDA, in the strongest possible terms, to carefully evaluate in its consumer research studies the use of footnotes in any form on the food label. All nutrition information provided on the food label should help consumers to make appropriate decisions related to good and bad diets rather than to raise concern about a particular food to such a level that other nutrition information is ignored. We hope that rather than move directly to testing of wording or placement of footnotes, that FDA will carefully examine the impact of using footnotes for nutrition labeling purposes.

### "Trans Fat Free" Nutrient Content Claim

NAMM believes that the agency's authorization of a defined nutrient content claim for "trans fat free" (and appropriate synonyms, e.g., "free of trans fat") would assist consumers in better identifying foods free of trans fat and would encourage industry to remove trans fat from foods, where feasible. NAMM suggests that the agency define "trans fat free" based on a level of trans fat that can be declared as zero (i.e., less than 0.5 g trans fat per reference amount and per serving, 21 CFR 101.9(c)(2)(ii)), and based on a

level of saturated fat that is consistent with recommendations of the National Academy of Sciences (NAS) and National Institutes of Health (NIH).

NAMM believes that an appropriate level of saturated fat for purposes of making a "trans fat free" claim need not be zero. As the NAS has stated, "It is neither possible nor advisable to achieve 0 percent of energy from saturated fatty acids in typical whole-food diets. ... Because saturated fatty acids are unavoidable in ordinary diets, consuming 0 percent of energy would require extraordinary changes in patterns of dietary intake."<sup>1</sup> NAMM proposes that an appropriate level of saturated fat for purposes of making a "trans fat free" claim be defined as 25% or less of fat as saturated fat. Our rationale follows.

The NAS, in its 2002 "Macronutrient Report" established an acceptable micronutrient distribution range (AMDR) for fat of 20 to 35% of energy.<sup>2</sup> This report also concluded, "...if all of the dietary fat consumed were to be low in saturated fatty acids (e.g., 20 percent of fat energy), a total fat intake of 35 percent of fat energy would yield a saturated fatty [acid] intake of 7 percent of total energy."<sup>3</sup> NAS is clearly indicating that a saturated fat level of 7% of total energy can be considered appropriately "low" in the context of an overall diet.<sup>4</sup> NIH further supports this position in the Third Report of the National Cholesterol Education Program, which establishes a recommended intake level for saturated fat of "less than 7% of total calories."<sup>5</sup>

Assuming the diet meets the 7% criterion discussed above and using the AMDR for total fat of 20 to 35% of energy:

- At a low level of total fat consumption (20% of energy), saturated fat could represent up to 35% of total fat.
- At a high level of total fat consumption (35% of energy), saturated fat could represent up to 20 % of total fat.
- At the midpoint level of recommended "acceptable" total fat consumption (28% of energy), saturated fat could represent up to 25% of total fat.

When evaluating whether a specific food is generally consistent with a diet that contains a minimal amount of saturated fat, NAMM asserts that it is reasonable to rely on the midpoint of the AMDR as described above as the basis for a "trans fat free" criterion of 25% or less of fat as saturated fat.

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<sup>1</sup> NAS, Institute of Medicine, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids (Macronutrients)* (2002), at 8-1.

<sup>2</sup> Id. at 8-1, 11-1.

<sup>3</sup> Id. at 11-22

<sup>4</sup> Based on a 2,000 calorie diet, 7% of total energy would represent about 140 calories, or about 15.5 g saturated fat. This is lower than the established DRV of 20 g saturated fat.

<sup>5</sup> NIH, National Heart, Lung, and Blood Institute, *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) (Final Report)* (NIH Pub. No. 02-5215) (September 2002), at V-4, V-9.

NAMM, therefore, recommends that FDA adopt a definition of "trans fat free" as "less than 0.5g trans fat per reference amount and per serving and 25% or less of fat as saturated fat." This approach would provide useful information about trans fat content of a food to consumers, while at the same time assuring that the overall composition of the food is generally consistent with a diet that is appropriately low in saturated fat. Further, NAMM notes that, because this approach is based on statements of the NAS and NIH, it could be the subject of an authoritative statement notification pursuant to 21 USC 343(r)(2)(G), and NAMM would support such a notification.

To ensure that the consumer is given a proper context within which to understand the significance of a "trans fat free" nutrient content claim, NAMM also recommends that the following statement accompany a "trans fat free" claim for any food that contains saturated fat at 0.5g or more per reference amount or per serving: "See nutrition information for saturated fat content".

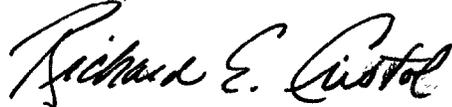
In conclusion, NAMM strongly recommends that FDA authorize a "trans fat free" claim for a food that contains:

- Less than 0.5g trans fat per reference amount and per serving, and
- 25% or less of total fat as saturated fat

provided that, on any food that contains 0.5g or more saturated fat per reference amount or per serving, the claim is accompanied by the statement, "See nutrition information for saturated fat content".

Thank you for your consideration of our comments.

Sincerely,

A handwritten signature in black ink that reads "Richard E. Cristol". The signature is written in a cursive, flowing style.

Richard E. Cristol  
President

**Docket Management Comment Form****Docket: 2003N-0076 - Food Labeling: Trans Fatty Acids in nutrition Labeling;  
Consumer Research to Consider Nutrient Content and Health Claims and Possible  
Footnote or Disclosure Statements**

You may use this electronic form to submit a comment to FDA on selected docket. All comments become part of the official public record and may be Published on the FDA Website.

FDA is in the process of moving to a new ISP. During this transition, the capability to attach documents to your comment will not be available. When the move is complete, the attach document functionality will be added to the E-comments Form.

[Docket Summary Report](#)

<i>(Required)</i>		
<b>Title</b>	<b>First Name</b>	<b>Last Name</b>
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**Cancel/Exit** - Abandon the comment and leave the application

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