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December 16, 2002

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

Re: Docket No. 94P-0036; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period

Dear Sir or Madam:

The National Association of Margarine Manufacturers (NAMM) appreciates this opportunity to comment on the Food and Drug Administration's (FDA) amended proposed rule to require declaration of *trans* fatty acids in nutrition labeling. 67 Fed. Reg. 69171 (Nov. 15, 2002). NAMM urges the FDA to withdraw its amended proposal to require a footnote warning consumers against consumption of *trans* fat.

Founded in 1936, NAMM is the national trade association representing manufacturers and marketers of margarine and vegetable oil spreads and their suppliers. While margarine is defined by a standard of identity that requires no less than 80 percent total fat, the "margarine" category is today comprised of a wide variety of non-standardized vegetable oil spreads that typically contain significantly lower levels of total fat, saturated fat, and *trans* fat than standardized margarine. Many of these products have been reformulated to contain little or no *trans* fat. Therefore, NAMM has a strong interest in ensuring that nutrition labeling provides consumers with information about *trans* fat and saturated fat content in an accurate, non-misleading, and non-alarming way.

NAMM strongly opposes the proposed footnote ("Intake of *trans* fat should be as low as possible"), because we believe it would be misleading and would result in consumers making unintended decisions with respect to healthy food choices. We believe the proposed footnote is tantamount to a warning statement. Rather than

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informing consumers as to the significance of *trans* fat in the daily diet, as FDA suggests, this footnote would convey a misleading negative impression as to the relative significance of *trans* fat compared to any other macronutrient on the nutrition label, particularly saturated fat. By suggesting that *trans* fat is to be avoided completely -- the ultimate meaning of "as low as possible" -- the proposed footnote puts all the focus on *trans* fat and defeats the larger purpose of assisting consumers in reducing the combined total of saturated fat and *trans* fat in their diets. See 64 Fed. Reg. 62746, 62755 (Nov. 17, 1999).

1. The proposed footnote will be perceived by consumers as a warning label.

"Intake of *trans* fat should be as low as possible" can only be read as "make every effort to eliminate *trans* fat from your diet or unfavorable consequences will result". The proposed footnote says to the consumer that no level of *trans* fat is acceptable for consumption, and hence, any product containing *trans* fat should be avoided.

This warning is not consistent with the advice of the National Academy of Sciences' Institute of Medicine (IOM), on which it is based. The IOM report, in its conclusion, "recommends that *trans* fatty acid consumption be as low as possible *while consuming a nutritionally adequate diet*" (emphasis added).¹ That critical qualifying phrase (*i.e.*, "while consuming a nutritionally adequate diet"), omitted by FDA in the proposed footnote, is there for an important reason. According to the IOM, changes in the diet to eliminate *trans* fat would "introduce undesirable effects.... and unknown and unquantifiable health risks", principally from reducing intake of protein and certain micronutrients that are often present in formulations also containing *trans* fatty acids.² If, in response to the proposed footnote, consumers eliminate *trans* fat from their diets, they will expose themselves to the "undesirable effects" and "unquantifiable health risks" that the IOM cautioned against.

The proposed footnote is inconsistent with IOM recommendations in another respect. The IOM report does not recommend, and provides no basis for, singling out *trans* fat from saturated fat and cholesterol. Because the IOM concluded that it could not set a Tolerable Upper Intake Level (UL) for *trans* fat, FDA determined it could not establish a Daily Value for *trans* fat. In the absence of a Daily Value, FDA is proposing this footnote to communicate to consumers the significance of *trans* fat in the daily diet. There are, however, other macronutrients that appear on the nutrition label for which the

¹ Institute of Medicine, "Letter Report on Dietary Reference Intakes for Trans Fatty Acids" (July 10, 2002), p. 14.

² *Id.* See also, Institute of Medicine, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (IOM Macronutrient Report), p. 8-66.

IOM was also unable to set a UL (e.g., saturated fat and cholesterol). In fact, the IOM advice regarding intake of saturated fat and cholesterol is essentially identical to its advice regarding intake of *trans* fat.³ Yet, FDA is not proposing a footnote/warning for saturated fat or cholesterol. FDA has offered no rationale why a footnote/warning should be required for *trans* fat, but not for these other macronutrients. Warning footnotes for any of these macronutrients are not justified by their scientific evaluations.

The IOM advice cannot be accurately summed up by the seemingly simple “soundbite” in FDA’s proposed footnote. NAMM believes that FDA is moving too quickly to adopt the findings of the IOM Macronutrient Report without fully thinking through the consequences, particularly since at this time FDA (together with the U.S. Department of Agriculture and Health Canada) is sponsoring a study entitled, “Use of Dietary Reference Intakes in Nutrition Labeling”. This study, being undertaken by the IOM, is expressly for the purpose of determining how best to integrate the new Dietary Reference Intakes (DRI’s), addressed in the IOM Macronutrient Report, into regulatory policy. Adopting the DRI’s piecemeal is a prescription for confusion and error.

2. The proposed footnote would confuse consumers about the relative impact of saturated fat and *trans* fat in the diet and result in undesirable consumer behavior.

The proposed footnote conveys a misleading message about the relative merits of saturated fat and *trans* fat. The proposed footnote advises consumers that their intake of *trans* fat should be “as low as possible,” meaning eliminate *trans* fats from their diets. When this advice is read in the context of the existing nutrition label, particularly the existing Daily Value of 20 grams (g) saturated fat, the message to consumers is that a healthy diet consists of up to 20 g of saturated fat per day, but no *trans* fat.

Using this approach, FDA would be sending consumers a nutrition message we hope the agency does not intend to communicate. From the beginning of the *trans* fat labeling rulemaking, FDA has made clear that its purpose is to encourage consumers to reduce their consumption of the combined total of saturated fat and *trans* fat. If labeling of *trans* fat with the proposed footnote were to divert consumers attention away from reducing total fat and saturated fat along with *trans* fat, as NAMM believes it would, FDA would defeat its stated purpose. As FDA has noted, from a public health perspective, saturated fat intake is the greater concern, because Americans generally consume far more saturated fat than *trans* fat. According to the agency:

³ “While increased serum low density lipoprotein (LDL) cholesterol concentrations, and therefore risk of coronary heart disease, may increase at high intakes of saturated fatty acids, *trans* fatty acids, or cholesterol, a UL is not set for these fats because the level at which risk begins to increase is very low and cannot be achieved by usual diets and still have adequate intakes of all other required nutrients. It is thus recommended that saturated fatty acid, *trans* fatty acid, and cholesterol consumption be as low as possible while consuming a nutritionally adequate diet.” IOM, Macronutrient Report, p. S-4.

FDA does not want to distract consumers from years of consumer education messages about saturated fat, especially because the average intake of saturated fat exceeds the average intake of *trans* fat by about fivefold (approximately 25g versus 5 g/day, respectively).

See 64 Fed. Reg. at 62755 (Nov. 17, 1999).

The comparison of a serving of a typical tub "margarine" product like a 70% vegetable oil spread with a serving of butter clearly illustrates the great potential for consumer confusion and undesirable response.

	<u>70% Vegetable Oil Spread</u>	<u>Butter</u>
Total Fat	10 grams	11 grams
Saturated Fat	2 grams	7 grams
<i>Trans</i> Fatty Acids	2 grams*	0 grams
Cholesterol	0 milligrams	31 milligrams

*Intake of *trans* fat should be as low as possible

The presence of the proposed footnote takes much of the focus away from the other nutrients declared in the Nutrition Facts box and will result, in this case, in causing many consumers to choose butter which has almost twice as much combined saturated fat and *trans* fat as this popular margarine product in addition to cholesterol which is not present in margarine products. The National Cholesterol Education Program and the American Heart Association have repeatedly and emphatically recommended soft margarine products over butter.

Even a Q&A document issued by FDA in conjunction with its initial proposal on *trans* fat labeling⁴ clearly states that margarine, compared to butter, is the healthier table spread, but consumer behavior -- measured by market research studies, opinion surveys and purchase patterns -- demonstrates that this message is failing to reach consumers who mistakenly confuse news about *trans* fats. A major effort by the margarine industry to communicate to the consumer and considerable progress in substantially reducing *trans* fat in margarine products have led to reducing this confusion. FDA's proposed footnote would set back these efforts.⁵

⁴ FDA, "Questions and Answers on *Trans* Fat Proposed Rule" (Nov. 1999).

⁵ In its April 17, 2000 comments, NAMM argued that naturally-occurring *trans* fats, including conjugated linoleic acid (CLA), present in butter and other dairy foods should be included in the regulatory definition of "*trans* fat" and required to be declared in the nutrition label. NAMM continues to believe this, and we note that the IOM Macronutrient Report includes CLA in the definition of *trans* fat. If FDA were to adopt the IOM definition of *trans* fat, some butter products would likely exceed the 0.5 g threshold for declaration of *trans* fat. Even in that case,

In addition to greater consumption of butter, consumers are also likely to substitute saturated fat for *trans* fat in their diets generally because of the proposed footnote. If the nutrition label tells consumers that the recommended intake of *trans* fat is 0 g and the recommended intake of saturated fat is 20 g/day, then many consumers are likely to increase their intake of saturated fat in an effort to avoid *trans* fat. Because saturated fats are generally derived from animal sources, this is likely to lead to increased intake of cholesterol as well.

3. The proposed footnote would result in substitution of saturated fat for *trans* fat by food processors.

By stigmatizing *trans* fat, the proposed footnote would create strong pressure on food processors to remove all, or virtually all, *trans* fat from many products. To avoid having the footnote, many food processors are likely to reformulate their products to remove *trans* fat. Unfortunately, *trans* fat is likely to be replaced largely with saturated fat. As NAMM explained in earlier comments submitted in this rulemaking,⁶ the most obvious way to reduce the amount of *trans* fat in any food product is to increase the amount of saturated fat. While some proprietary technologies have enabled some food processors, particularly in the margarine industry, to reduce *trans* fat without increasing saturated fat, these technologies, in many cases, result in a product with limited functionality and consumer appeal.

The end result is likely to be products with higher levels of saturated fat. For example, in order to avoid the *trans* fat footnote, a bakery given the choice of ingredients might make its product with butter instead of margarine or vegetable oil spread.

NAMM believes that the quantitative declaration of *trans* fat alone will create a competitive incentive for food processors within the same product categories to make every effort to reduce *trans* fat. The quantitative declaration would accelerate the evolutionary trend away from *trans* fat that is already underway. The proposed footnote, however, would turn this trend into a stampede to the easiest substitute for *trans* fat, saturated fat.

however, the proposed footnote would still stigmatize margarine and vegetable oil spreads by overemphasizing the two products' *trans* fat levels and de-emphasizing the more important comparison between levels of combined saturated fat and *trans* fat. FDA's position to-date to not recognize conjugated linoleic acids as *trans* fats, as the IOM Macronutrient Report does, has a material bearing on whether a product can declare zero *trans* fat on its nutrition label. If FDA is going to follow the advice of the IOM report, the agency's treatment of conjugated linoleic acid with respect to the definition of *trans* fat should be reconciled with the IOM report.

⁶ See NAMM comments dated April 17, 2000.

4. There are already other footnotes on the nutrition label. The addition of yet another footnote contributes to more clutter and moves further away from simplicity for consumer understanding.

Every Nutrition Facts label already has at least one required asterisk and footnote. That asterisk appears next to the Daily Value heading and refers to a footnote at the bottom of the Nutrition Facts box, i.e., "**Percent Daily Values are based on a 2000 calorie diet". And many packaged products use asterisks on the nutrition panel and corresponding footnotes to meet other labeling requirements. Products used for baking, for example a popular brownie mix, uses asterisks on the nutrition panel to differentiate nutrient levels in the "mix" and "as prepared" with footnotes enumerating the other ingredients upon which the "as prepared" values are calculated. Many products also feature another footnote at the base of the Nutrition Facts box, i.e., "Not a significant source of [nutrients]". All in all, there is already too much information for the busy consumer to make simple choices without yet one more footnote and a misleading one at that.

5. The proposed footnote is subject to challenge on constitutional grounds.

As discussed above, we believe that the proposed footnote is misleading and that a food product bearing the footnote would therefore be misbranded under § 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(a)). In addition, NAMM believes the proposed footnote raises First Amendment concerns.

The First Amendment protects "both the right to speak freely and the right to refrain from speaking at all." *Wooley v. Maynard*, 430 U.S. 705, 714 (1977). For commercial speech, the Supreme Court has held that government regulation, including regulations that compel speech, must be calibrated to advance a substantial government interest. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980). Under the *Central Hudson* test, a regulatory agency must assert a substantial government interest, must show that its regulation directly advances that interest, and must show that its regulation is not more extensive than is necessary to achieve its purpose.

NAMM believes that the proposed *trans* fat footnote fails the *Central Hudson* test. While the FDA has asserted a substantial government interest (i.e., providing consumers with information about the amounts of nutrients that may increase their risk of heart disease, and the significance of those amounts in their daily diet), the proposed footnote does not directly advance that asserted interest. As explained above, the proposed footnote conveys a misleading message by implying that a healthy diet may consist of 20 g of saturated fat but no, or virtually no, *trans* fat. In doing so, the proposed footnote would lead to a substitution of saturated fat for *trans* fat. The net effect is likely to be an increase in the combined total of saturated fat and *trans* fat consumed by the average American.

The proposed footnote also fails the final prong of the *Central Hudson* test. It is more extensive than is necessary to achieve its purpose. The proposed footnote is tantamount to a warning statement about *trans* fat.⁷ A government regulation requiring “the functional equivalent of a warning” is unlikely to pass constitutional muster absent a compelling public health justification. See *International Dairy Foods Association v. Amestoy*, 92 F.3d 67, 73 (2d Cir. 1996). While a more recent court case upheld a government regulation compelling commercial speech, it did so because the compelled speech in that case was factual and accurate, whereas the proposed footnote is hortatory and misleading. See *National Electric Manufacturers Association v. Sorrell*, 272 F.3d 104 (2d Cir. 2001).

6. The proposal by FDA to exercise its enforcement discretion to permit labels to include the proposed footnote prior to publication of a final rule is a mistake.

Some food processors making products which have no *trans* fats may see a short-term competitive advantage to tie a quantitative declaration of zero *trans* fat to the proposed alarming footnote/warning. FDA’s proposal to allow this (*i.e.*, declaration of *trans* fat in combination with the proposed footnote) prior to publication of a final rule is unwise. In addition to prematurely permitting the proposed footnote before FDA has the opportunity to review public comments about it, NAMM believes it is not good regulatory policy to establish such a precedent-setting label device prior to the issuance of final regulations. NAMM does not object, however, to the exercise of the FDA’s enforcement discretion now with respect to permitting the quantitative declaration of *trans* fat.

7. Summary

In summary, although NAMM supports the quantitative declaration of *trans* fats on the nutrition label and believes a final regulation requiring this quantitative declaration should be published as soon as possible, we believe the footnote proposed in FDA’s amended proposed rule of November 15, 2002 to label *trans* fatty acids is not appropriate for the following reasons:

- The proposed footnote will be perceived by consumers as a warning label.
- The proposed footnote will cause consumer confusion about the relative impact of saturated fat and *trans* fat in the diet and result in undesirable

⁷ It is worth noting again that the language in the proposed footnote does not accurately reflect the IOM recommendation on *trans* fat intake. The IOM Macronutrient Report recommends that intake of *trans* fat should be “as low as possible while consuming a nutritionally adequate diet.” By omitting the words “while consuming a nutritionally adequate diet,” the proposed footnote changes the meaning of the IOM recommendation, suggesting no allowance for *trans* fat in a healthy diet.

consumer behavior leading to the consumption of higher levels of saturated fat.

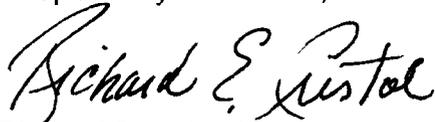
- The proposed footnote will encourage food processors to substitute saturated fat for *trans* fat, which consumers will perceive as more healthful.
- The proposed footnote will result in more label clutter, moving away from simple messages needed to influence appropriate consumer action.
- The proposed footnote is misleading and may, therefore, be found to be unconstitutional.

In addition, NAMM believes that permitting food processors to use the proposed footnote now, under FDA's exercise of enforcement discretion, is premature.

Therefore, NAMM respectfully requests FDA to withdraw its proposed amendment and to delete the proposed footnote from its final rule on *trans* fat labeling.

The National Association of Margarine Manufacturers appreciates this opportunity to comment on this very important issue.

Respectfully submitted,

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

Richard E. Cristol
President