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Dockets Management Branch  
Food and Drug Administration  
.5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 02N-0209; Request for Comment on First Amendment Issues

The National Association of Margarine Manufacturers (NAMM) appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) regarding the agency's Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002) ("Comment Request"). NAMM applauds FDA's stated desire to ensure that its regulations, guidances, policies, and practices are in compliance with the prevailing law on First Amendment protections of commercial free speech.

Founded in 1936, NAMM is the national trade association representing manufacturers and marketers of margarine and vegetable oil spreads and their suppliers. These products, made predominantly from vegetable oils, contain no cholesterol and relatively low levels of saturated fat. Many of these products have been reformulated to contain little or no trans fatty acids. While margarine must contain no less than 80 percent total fat pursuant to an FDA standard of identity, the "margarine" category is now comprised primarily of a wide variety of vegetable oil spreads that typically contain much lower levels of total fat, saturated fat, and *trans* fat than standardized margarine. These products are sought out by consumers because they represent healthy alternatives to butter and other toppings, which contain cholesterol and higher levels of total fat and saturated fat.

NAMM's comments address two questions posed by the Comment Request:

8. Do FDA's speech-related regulations advance the public health concerns they are designed to address? Are there other alternative approaches that FDA could pursue to accomplish those objectives with fewer restrictions on speech?

9. Are there any regulations, guidance, policies, and practices FDA should change in light of governing First Amendment authority?

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NAMM believes there are serious First Amendment concerns regarding:

- Existing FDA regulations that absolutely prohibit the nutrient content claims “no cholesterol” and “low cholesterol” if the amount of saturated fat in a food exceeds a certain level. 21 C.F.R. § 101.62(d)(1)(ii)(C), 101.62(d)(2)(iii)(B).
- FDA’s proposed rule on labeling of *trans* fatty acids which would prohibit a variety of nutrient content claims in foods that contain *trans* fat above a specified level. 64 Fed. Reg. 62746 (Nov. 17, 1999).

Each of these issues is discussed separately below.

## **BACKGROUND ON MARGARINE AND VEGETABLE OIL SPREAD**

Margarines and vegetable oil spreads are toppings made predominantly from vegetable oils. While margarine is governed by an FDA standard of identity (21 C.F.R. § 166.110) which dictates that it must contain at least 80 percent total fat, vegetable oil spreads (and margarines that have been modified to qualify for use of a nutrient content claim pursuant to 21 C.F.R. § 130.10) generally contain significantly lower levels of total fat. In contrast to butter, margarines and spreads contain no cholesterol and significantly less saturated fat. Many margarines and spreads have also been reformulated to contain little or no *trans* fatty acids.

The margarine/spread industry is proud of the progress it has made in reducing the total fat and the combined saturated fat and *trans* fat content of its products. As a group, margarines and spreads are significantly more heart-healthy (i.e., no cholesterol and lower in fat and saturated fat) than butter. For example, margarine and spread products have an average total fat content of approximately 56 percent, compared to 80 percent for butter. (Industry data from marketplace scans and other research sources). Full-fat stick margarines with 80 percent total fat typically contain only 4 grams (g) of saturated fat and *trans* fat combined, compared to 7.5 g of combined saturated fat and *trans* fat for butter. Thus, even full-fat stick margarines, which represent a small share of the total margarine and spread marketplace, have 50 percent less combined saturated fat and *trans* fat than butter. The difference between more typical spread products and butter is even more dramatic. Unfortunately, many consumers are unaware of this progress.

To highlight the difference between margarine and spread products on the one hand and butter on the other, margarine and spread manufacturers need to be able to use truthful and non-misleading nutrient content claims. To reach consumers who remain confused by the “margarine versus butter” debate, it is essential that margarine and spread labels be able to use nutrient content claims that characterize the levels of cholesterol, saturated fat, and/or *trans* fat in their products.

Current FDA regulations, however, prevent margarines and spreads from using the nutrient content claims “no cholesterol” and “low cholesterol” if the amount of saturated fat in

the product exceeds a certain level. Thus, even though a margarine contains no cholesterol, it is nevertheless prohibited from making a “no cholesterol” nutrient content claim if it contains more than 2 g of saturated fat per labeled serving. The result is that a margarine and spread product with 0 milligrams (mg) of cholesterol and 2.4 g of saturated fat is treated the same as a butter with 30 mg of cholesterol and 7 g of saturated fat – both are prohibited from making a “no cholesterol” claim. In addition, FDA appears to be moving towards an even more restrictive approach to nutrient content claims. Under FDA’s proposed rule on labeling of *trans* fatty acids, all nutrient content claims for saturated fat or cholesterol would be prohibited for foods that contain *trans* fat above a certain threshold.

## **FIRST AMENDMENT PROTECTION OF COMMERCIAL SPEECH**

The First Amendment “protects commercial speech from unwarranted governmental regulation.” Central Hudson Gas & Electric Corp. v. Public Service Com’n of New York, 447 U.S. 557, 561 (1980). The U.S. Supreme Court has stated that “the free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.” Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 646 (1985).

The U.S. Supreme Court has enunciated a four-part test for determining whether government regulation of commercial speech is constitutionally permissible:

- (1) To enjoy any First Amendment protection, commercial speech must concern lawful activity and may not be misleading.
- (2) If commercial speech is protected, is the asserted government interest in restricting speech substantial?
- (3) If the asserted government interest is substantial, does the government restriction directly advance that interest?
- (4) If the government restriction directly advances a substantial government interest, is the restriction no more extensive than is necessary to serve that interest?

Central Hudson, 447 U.S. at 566.

With regard to the first prong of the Central Hudson test, the courts have drawn a distinction between commercial speech that is *inherently misleading* and that which is only *potentially misleading*. The government may absolutely prohibit commercial speech that is inherently misleading, but may not completely ban commercial speech that is potentially misleading. Peel v. Attorney Reg. & Disciplinary Com’n, 110 S.Ct. 2281, 2292-93 (1990) (government may not “completely ban statements that are not actually or inherently misleading”). If the commercial speech in question is only potentially misleading, government restrictions of such speech must be analyzed under the Central Hudson test and are constitutionally permissible only if they directly advance a substantial government interest without imposing unnecessary burdens. Pearson v. Shalala, 164 F.3d 650, 655-56 (D.C. Cir. 1999).

## **FDA REGULATIONS PROHIBITING NUTRIENT CONTENT CLAIMS “NO CHOLESTEROL” AND “LOW CHOLESTEROL” FOR FOODS WITH MORE THAN 2 GRAMS OF SATURATED FAT ARE UNCONSTITUTIONAL**

FDA regulations prohibit use of the nutrient content claims “no cholesterol” and “low cholesterol” in labeling of foods that contain more than 2 g of saturated fat per reference amount customarily consumed (RACC). 21 C.F.R. §§ 101.62(d)(1)(ii)(C), 101.62(d)(2)(iii)(B). A “no cholesterol” claim on a food that contains no cholesterol is clearly truthful. However, FDA has determined that any cholesterol content claim on a food that contains more than 2 g of saturated fat per RACC is misleading. In the preamble to its final rule, FDA explained its determination:

.... an FDA survey has found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart disease.... Consequently, FDA continues to believe that to ensure that cholesterol claims do not mislead consumers it is necessary to permit their use only when the foods also contain levels of saturated fat that are below a specified threshold level.... The agency does not agree that disclosure of the amount of saturated fat in proximity to a cholesterol claim is sufficient to prevent consumers from being misled.

58 Fed. Reg. 2302, 2333-34 (Jan. 6, 1993). Thus, FDA concluded that a “no cholesterol” claim on a food such as a margarine or vegetable oil spread product, although truthful, must be prohibited because consumers would interpret any claim about cholesterol in a food to mean that the food will lower their blood cholesterol and this misleading impression could not be cured by a prominent disclosure of the food’s saturated fat content. On the other hand, FDA did not ban “no cholesterol” claims on foods high in total fat, because “total fat per se does not affect blood cholesterol levels.” Id.<sup>1</sup>

NAMM questions FDA’s determination as a matter of public policy. Based on a single consumer survey, FDA concluded that the average consumer would regard a “no cholesterol” claim as a health claim that the food will lower their blood cholesterol. FDA’s conclusion assumes a high level of consumer confusion about the difference between nutrient content claims and health claims, as well as the difference between cholesterol in food and blood cholesterol.<sup>2</sup>

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<sup>1</sup> FDA’s flat prohibition of cholesterol content claims in foods with more than 2 g of saturated fat per RACC stands in stark contrast to its general approach to nutrient content claims for foods high in saturated fat. A food with more than 4 g of saturated fat may bear other nutrient content claims (e.g., “rich in calcium,” “no sodium”) provided the disclosure “see nutrition information for saturated fat content” appears adjacent to the claim. 21 C.F.R. § 101.13(h).

<sup>2</sup> FDA’s conclusion seems to assume that consumers are unaware that nutrients other than cholesterol (i.e., saturated fat) also raise serum cholesterol levels. However, FDA itself recently stated that consumers *are* aware that saturated fat raises serum cholesterol levels. This was the agency’s rationale for proposing in 1999 that *trans* fatty acids and saturated fatty acids be declared

NAMM believes there should be a strong presumption that “no cholesterol” on a food label means that the food contains no cholesterol, period. FDA has the burden of showing that cholesterol content claims would be misunderstood, and a single, decade-old survey does not satisfy this burden.<sup>3</sup>

More importantly for purposes of these comments, FDA’s rationale for prohibiting “no cholesterol” claims for margarine and spread runs directly contrary to the Supreme Court’s decision in Central Hudson. Pursuant to that decision, commercial speech may be banned only if it is *inherently misleading*. A truthful “no cholesterol” claim on the label of a margarine or spread cannot be said to be inherently misleading, especially since information about the food’s saturated fat content is clearly stated in the Nutrition Facts panel. Where commercial speech is only *potentially misleading*, Central Hudson directs that the government find a method other than prohibition to address its concerns. NAMM doubts that a truthful “no cholesterol” claim for a margarine or spread is even potentially misleading. However, even if it were, the proximate disclosure of the food’s saturated fat content would be the appropriate and less restrictive approach.

#### **FDA’S PROPOSED RULE TO REQUIRE LABELING OF *TRANS* FATTY ACIDS IS CONSTITUTIONALLY FLAWED**

For the same reasons, NAMM believes that FDA’s proposed rule to require labeling of *trans* fatty acids may also run afoul of the First Amendment.<sup>4</sup> The proposed rule would prohibit a variety of nutrient content claims for foods that contain more than a specified level of *trans* fat. For example, it would prohibit a “no cholesterol” claim for any food that contains more than 2 g of saturated fat and *trans* fat combined per reference amount. As discussed above, NAMM believes that a “no cholesterol” claim is understood by most consumers to mean that the food contains no cholesterol. Because the claim is not misleading, a ban on cholesterol content claims

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together as “saturated fat.” FDA reasoned that consumers are aware that saturated fat raises serum cholesterol, but are not yet aware that *trans* fat has this effect. 64 Fed. Reg. at 62746.

<sup>3</sup> It is noteworthy that a food’s cholesterol content cannot disqualify it from making a “no saturated fat” claim. Instead, FDA requires that a “no saturated fat” claim be accompanied by a disclosure of the food’s cholesterol content in immediate proximity to the claim. 21 C.F.R. § 101.62(c). FDA has not explained the reason for this difference between “no cholesterol” and “no saturated fat” claims. Both dietary cholesterol and saturated fat are recognized as nutrients that raise serum cholesterol levels; both are required to be declared in Nutrition Facts; and FDA has set Daily Reference Values for both.

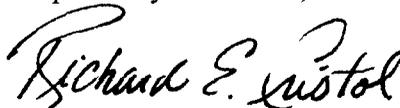
<sup>4</sup> The proposed rule would require that *trans* fat be included in the declaration for saturated fat in Nutrition Facts, even though the two substances are chemically distinct. NAMM believes that this aspect of the proposed rule is problematic under the First Amendment, because it would compel commercial speech that is scientifically inaccurate. However, we understand that FDA has said it intends to require separate declaration of *trans* fat content in Nutrition Facts.

based on a food's saturated fat or *trans* fat content, or the two combined, is constitutionally suspect.

### **CONCLUSION**

In conclusion FDA should only prohibit truthful label statements, where it can demonstrate either: (1) the banned statements are inherently misleading; or (2) the prohibition of such statements otherwise passes muster under the Central Hudson test. In the case of its regulations defining the nutrient content claims "no cholesterol" and "low cholesterol," FDA has not met its Constitutional burden. These regulations absolutely prohibit a food that contains no cholesterol, such as a margarine or spread, from making a truthful "no cholesterol" claim if the food contains more than 2 g of saturated fat. Yet, FDA has not established that such a claim is inherently misleading. Nor has FDA shown that its restriction is no more extensive than is necessary to serve the government interest in preventing consumer deception. NAMM therefore requests that FDA amend its regulations to delete 21 C.F.R. §§ 101.63(d)(1)(ii)(C) and 101.62(d)(2)(iii)(B).

Respectfully submitted,

A handwritten signature in black ink that reads "Richard E. Cristol". The signature is written in a cursive style with a large, prominent initial "R".

Richard E. Cristol  
President