Chocolate Manufacturers Association
National Confectioners Association
8320 Old Courthouse Road
Suite 300
Vienna, VA 22182
CMA (703) 790-5011 NCA (703) 790-5750

October 9, 2003

2003 OCT -9 P2:47

BY HAND DELIVERY

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

Re: Docket No. 03N-0076; Food Labeling: *Trans* Fatty Acids in Nutrition Labeling

The National Confectioners Association (NCA) and the Chocolate Manufacturers Association (CMA) appreciate this opportunity to submit comments on the Food and Drug Administration's (FDA) advance notice of proposed rulemaking regarding *trans* fatty acids in nutrient content claims, health claims, and a possible footnote or disclosure statement. 68 Fed. Reg. 41,507 (July 11, 2003).

NCA is the national, not-for-profit trade association representing more than 650 confectionery manufacturers and suppliers. CMA is the national, not-for-profit trade association representing the majority of chocolate manufacturers in the United States. CMA members produce over 90 percent of all chocolate manufactured in this country. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture and market a wide variety of finished chocolate and chocolate-containing confectionery products for the consumer market.

NCA and CMA believe that the best way to educate consumers about *trans* fat, and to encourage food manufacturers to reduce *trans* fat in their products, is to authorize new nutrient content claims and health claims about *trans* fat. The Nutrition Facts panel will soon include a separate line item declaration for *trans* fat. The new declaration of *trans* fat in Nutrition Facts, together with new health claims and nutrient content claims, the upcoming revision of the *Dietary Guidelines for Americans*, and media coverage, will be more than sufficient to educate consumers of the benefits of limiting consumption of *trans* fat and saturated fat. Requiring food labels to include a footnote or other mandated statement about *trans* fat, either alone or in combination with other nutrients, is both unnecessary and counterproductive.

03N-0076

C6

1. **NCA and CMA strongly oppose the use of a footnote regarding *trans* fat, either alone or in combination with saturated fat and cholesterol.**

NCA and CMA commend FDA for reconsidering its earlier proposal to require a footnote reading "Intake of *trans* fat should be as low as possible." We now urge FDA to scrap the footnote entirely. **NCA and CMA strongly oppose any mandatory footnote or other label statement containing nutritional advice regarding particular nutrients.**

A footnote advising consumers to limit intake of a particular nutrient, or nutrients, present in the labeled food would be a warning or disclosure statement about that food. FDA's long-standing policy is not to require a warning or disclosure statement unless a food makes a nutrient content claim and thereby encourages consumers to emphasize that food in their diets.[1] In the absence of a claim, FDA does not require warning or disclosure statements about particular nutrients, because "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease." 58 Fed. Reg. 2302, 2307 (Jan. 6, 1993). The same reasoning applies to *trans* fat.

Even if the label statement about *trans* fat is viewed as a dietary guidance statement, rather than a warning about the labeled food, it would still be a sharp departure from FDA's existing policy. FDA has never mandated dietary guidance statements on food labels, and we do not think FDA should begin doing so now. First, there are other, more appropriate avenues for communicating dietary guidance to the public. FDA and the U.S. Department of Agriculture have a number of educational tools, including the *Dietary Guidelines for Americans* and the Food Guide Pyramid, for disseminating dietary guidance. Manufacturers may present dietary advice about the consumption of particular nutrients on the food label in the form of health claims, nutrient content claims, structure/function claims, and dietary guidance statements.[2] Second, if FDA were to mandate use of a dietary guidance statement about *trans* fat, there would be tremendous pressure for the agency to mandate dietary guidance statements about other nutrients as well.

---

[1] Even where FDA has required a disclosure statement to accompany a nutrient content claim, the disclosure statements mandated by FDA have been neutral (*e.g.*, "see nutrition information for fat content"). 21 C.F.R. § 101.13(h)(1).

[2] While claims and dietary guidance statements are optional, FDA can exercise considerable control over their use by easing or strengthening restrictions governing their use. FDA recently stated it will publish an advance notice of proposed rulemaking regarding voluntary use of dietary guidance statements in food labeling. FDA, "FDA's Implementation of 'Qualified Health Claims': Questions and Answers (Aug. 27, 2003). If FDA were to provide industry with model dietary guidance statements about *trans* fat, saturated fat, and cholesterol, we have no doubt that many manufacturers would voluntarily add such dietary guidance statements to their product labels.

Importantly, mandating dietary guidance statements would raise serious First Amendment issues. Under the First Amendment, government regulation of commercial speech, including regulations that compel speech, must directly advance a substantial government interest and must be no more extensive than is necessary to achieve their purpose. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n. of New York*, 447 U.S. 557 (1980). Given the many other avenues that FDA can use to educate consumers about *trans* fat, a mandated label statement would be more extensive and burdensome than is necessary to advance any conceivable government interest.

Dietary guidance statements certainly do not belong in the Nutrition Facts panel. The Nutrition Facts panel was intended to provide consumers with quantitative information about the presence of certain nutrients in labeled foods. In addition, in order to explain to consumers the significance of that quantitative declaration in the context of a total daily diet, FDA requires a declaration of Percent Daily Value (%DV) for those nutrients that have been assigned a Daily Value. However, the Nutrition Facts panel was not intended to provide dietary advice in the manner FDA is contemplating. Consumers do not expect to see dietary guidance statements in the Nutrition Facts panel and will not look for them there. As a result, the footnote is not likely to be read by most consumers. Those consumers who do read it are likely to be confused by its presence.[3] Moreover, adding a dietary guidance statement to Nutrition Facts would make the Nutrition Facts panel unwieldy and unreadable. This would be especially problematic for manufacturers of foods with small packages, such as confectionery. The contemplated footnote, in addition to the new declaration of *trans* fat as a separate line item in Nutrition Facts, would be extremely difficult to fit on the small labels of many confectionery products. With the additional verbiage, consumers would be less likely to read the entire Nutrition Facts panel.

There is absolutely no need to mandate a warning or dietary guidance statement about *trans* fat, either alone or in combination with other lipids, when the same message can be conveyed to consumers by means of voluntary health claims and nutrient content claims. As discussed below, FDA should define the nutrient content claims "*trans* fat free" and "reduced *trans* fat." In addition, the agency should amend its regulation authorizing a health claim about saturated fat and cholesterol and the risk of coronary heart disease (21 C.F.R. § 101.75) to add *trans* fat. FDA should, as it has promised, provide industry with guidelines for voluntary use of dietary guidance statements and should propose model dietary guidance statements regarding *trans* fat. FDA also can make use of the extensive educational tools at its disposal, including the upcoming revision of the *Dietary Guidelines for Americans*, press releases, and other publications, to educate consumers about *trans* fat.

---

[3] In addition, it will not be clear to consumers why the significance of some nutrients in the daily diet is expressed using a %DV declaration, while the significance of other nutrients is explained using a footnote. The use of two different approaches to accomplish the same purpose is likely to confuse consumers.

2. NCA and CMA support new regulations defining the nutrient content claims "*trans* fat free" and "reduced *trans* fat."

NCA and CMA urge FDA to issue regulations defining the nutrient content claims "*trans* fat free" and "reduced *trans* fat." Use of these nutrient content claims will encourage consumers to limit their intake of *trans* fat and encourage manufacturers to reduce or eliminate *trans* fat in their products.

A food should be able to make a "*trans* fat free" claim if it contains less than 0.5 grams (g) of *trans* fat per reference amount customarily consumed (RACC).[4] The definition of "*trans* fat free" should include no limit on saturated fat content. NCA and CMA are of the view that FDA nutrition labeling regulations should distinguish between saturated fatty acids that increase serum total and LDL cholesterol levels and those that do not. There is a growing body of scientific evidence that stearic acid does not increase serum cholesterol.[5] Therefore, a limit on all saturated fatty acids should not be a condition for making this, or any other, nutrient content claim.

A food should be able to make a "reduced *trans* fat" claim based on a reduction of at least 25 percent in *trans* fat per RACC as compared to an appropriate reference food. For the reasons set forth above with regard to the claim "*trans* fat free," the definition of "reduced *trans* fat" also should include no limit on saturated fat.

---

[4] If a food making a "*trans* fat free" claim contains an ingredient generally understood by consumers to contain *trans* fat, the listing of that ingredient in the ingredients declaration should be followed by an asterisk that refers to the statement "adds a trivial amount of *trans* fat," or a similar statement, appearing below the ingredients declaration. A food not making a "*trans* fat free" claim should be allowed to use the same label statement to indicate that a particular ingredient adds a trivial amount of *trans* fat, provided such statement is truthful and not misleading.

[5] "In general, stearic acid has been shown to have a neutral effect on total and LDL cholesterol concentrations.... While palmitic, lauric, and myristic acids increase cholesterol concentrations..., stearic acid is more similar to oleic acid.... Furthermore, a stearic acid-rich diet has been shown to improve thrombogenic and atherogenic risk factor profiles...." Institute of Medicine, National Academy of Sciences, *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids* (2002), p. 8-49. "A 'probable' level of evidence demonstrates.... no relation for stearic acid [to risk of cardiovascular disease].... Stearic acid has not been shown to elevate blood cholesterol and is rapidly converted to oleic acid in vivo." World Health Organization, *Diet, Nutrition and the Prevention of Chronic Diseases* (2003), pp. 60-61. *See also,* a citizen petition submitted by the American Cocoa Research Institute and filed by FDA on April 4, 1996 (Docket No. 96P-0111/CP 1).

3. FDA should require that a disclosure statement about *trans* fat content accompany nutrient content claims about saturated fat and cholesterol content in order to prevent such claims from being misleading.

FDA is considering setting limits on *trans* fat in foods that make certain existing nutrient content claims about nutrients other than *trans* fat (*e.g.*, "low saturated fat"). Generally, FDA imposes a limit on a nutrient other than the nutrient that is the subject of a claim only when doing so is necessary to prevent the claim from being misleading. For example, because most consumers believe that a food making a "cholesterol free" claim does not raise serum cholesterol levels, FDA imposes a limit on the amount of saturated fat allowed in foods making this claim. Such limits generally are based on the Daily Value (DV) for the nutrient in question.

The problem with imposing limits on *trans* fat in foods making nutrient content claims about other nutrients is that FDA has not established a Daily Value for *trans* fat. In the absence of a DV for *trans* fat, FDA does not have a scientifically sound basis for setting limits on *trans* fat for existing nutrient content claims about saturated fat and cholesterol content.[6] It seems to us that any such limits would necessarily be arbitrary. This is particularly true of the claims "low saturated fat" and "low cholesterol," since FDA defines "low" claims exclusively in terms of Daily Values.

Instead of setting a *trans* fat limit for claims about saturated fat and cholesterol, we believe that FDA should require that a disclosure statement about *trans* fat (e.g., "see nutrition information for *trans* fat content") accompany those nutrient content claims if the labeled food contains *trans* fat (*i.e.*, if the food contains more than 0.5 g of *trans* fat per serving). For example, if a food that makes a "low saturated fat" claim contains more than 0.5 g of *trans* fat, the claim should be required to be accompanied by the disclosure statement "see nutrition information for *trans* fat content."

4. If FDA concludes it is necessary to set a disclosure/disqualifying level for *trans* fat, even in the absence of a Daily Value for *trans* fat, that level should take into account the lower prevalence of *trans* fat in the food supply and the scarcity of evidence that low intakes of *trans* fat increase risk of disease.

FDA is considering setting a disclosure level for *trans* fat, under 21 C.F.R. § 101.13(h)(1), and a disqualifying level for *trans* fat, under 21 C.F.R. § 101.14(a)(4). FDA's existing regulations establish disclosure/disqualifying levels for total fat, saturated fat, cholesterol, and sodium. In each case, the disclosure/disqualifying level is equal to 20 percent of the Daily Value for that nutrient. Using total fat as an example, FDA's reasoning is that consumption of 200 percent of the DV for fat is likely to increase risk of disease. FDA assumes that most people consume a total of 20 food/beverage items per day and that, given the uneven distribution of fat in the food supply, only

---

[6] FDA could assume a DV for *trans* fat without establishing one. However, we believe this would be inappropriate and would set a very unfortunate precedent.

about half of those items contain fat. Therefore, if an individual consumes 10 food items each having 20 percent of the DV for fat, that individual will have consumed 200 percent of the DV for fat.

Since all disclosure/disqualifying levels are based on Daily Values, there is no basis for FDA to set a disclosure/disqualifying level for *trans* fat without first establishing a DV for *trans* fat. However, if FDA believes that it must set a disclosure/disqualifying level for *trans* fat even in the absence of a *trans* fat DV, then CMA and NCA believe that any disclosure/disqualifying level for *trans* fat must be separate from the disclosure/disqualifying level for saturated fat. This is in keeping with the separate declaration for *trans* fat in Nutrition Facts and FDA's recognition that *trans* fat and saturated fat are distinct nutrients. In addition, any disclosure/disqualifying level for *trans* fat should take into account the fact that *trans* fat, while common in certain food product categories, is less prevalent in the overall food supply than either total fat or saturated fat. Lastly, it must reflect the fact that there is very little scientific evidence that *trans* fat at low levels of intake increases serum total or LDL cholesterol.

5. FDA should use its educational tools to clear up the confusion about "partially hydrogenated oils" and their relationship to *trans* fat.

Many stories in the media and some of FDA's own educational materials advise consumers that all foods listing partially hydrogenated oils in their ingredients declaration contain *trans* fat. This advice is not accurate. The fact that a food lists "partially hydrogenated oils" as an ingredient does not necessarily mean the food contains *trans* fat. Some of the new alternative "*trans* fat free" oils and shortenings on the market contain partially hydrogenated oils. Therefore, any message suggesting that consumers should avoid foods containing partially hydrogenated oils will be counterproductive, because it will discourage manufacturers from using these alternative products.

NCA and CMA urge FDA to do whatever it can to clear up the confusion surrounding partially hydrogenated oils. As a first step, we hope that FDA will correct any misleading messages in its own educational materials. In addition, where an ingredient that is required to be listed as "partially hydrogenated oil" adds only a trivial amount of *trans* fat, manufacturers should be permitted to use a statement below the ingredients declaration indicating this fact (*see* footnote 4 above).

* * * * *

We appreciate this opportunity to share our views with FDA.

Respectfully submitted,

Lawrence T. Graham /lac

Lawrence T. Graham
President
National Confectioners Association

Lynn Bragg /lac

Lynn Bragg
President
Chocolate Manufacturers Association