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**BY ELECTRONIC MAIL AND U.S. MAIL**

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket Nos. 1994P-0390 and 1995P-0241

The National Confectioners Association (NCA) and the Chocolate Manufacturers Association (CMA) are pleased to have this opportunity to comment on the Food and Drug Administration's (FDA) proposed rule to amend its regulations on nutrient content claims and health claims to provide greater flexibility in use of such claims in food labeling. 60 Fed. Reg. 66,206 (Dec. 21, 1995); 69 Fed. Reg. 24,541 (May 4, 2004).

NCA and CMA, non-profit industry trade associations with a historic relationship of working together for 21 years, collectively represent over 300 companies that manufacture and market the vast majority of chocolate and non-chocolate confectionery produced in the U.S.

We strongly support FDA's decision to proceed to completion of this rulemaking. Now that FDA, industry, and consumers have a decade of experience with nutrient content claims and health claims under the Nutrition Labeling and Education Act, it is time to refine some of the rules governing such claims. NCA and CMA agree with FDA's premise that there is a need to liberalize the general requirements for nutrient content claims and health claims, some of which are unnecessarily restrictive. Removing unnecessary restrictions is good law as well as good policy. Under the First Amendment, government restrictions on commercial speech may not be more extensive than is necessary to achieve a substantial government interest.<sup>1</sup> Some existing restrictions on nutrient content claims and health claims might not meet this test.

NCA and CMA believe the amendments proposed by FDA will encourage greater use of nutritional claims and enhance their value to consumers. We believe that all foods can fit into a well-balanced diet and healthy lifestyle, and we encourage FDA to provide consumers with more

<sup>1</sup> See, e.g., *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

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label information to enable individuals to make informed food choices. In several respects, we believe the FDA proposals should go further. Our specific comments follow.

**1. FDA should rescind the disqualifying level for total fat and should reconsider the disqualifying level for saturated fat.**

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that a health claim may only be made if the food for which the claim is made does not contain “any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet-related, taking into account the significance of the food in the total daily diet.” 21 U.S.C. § 343(r)(3)(A)(ii). However, FDA may allow a health claim for a food that exceeds a disqualifying nutrient level if the agency finds that allowing the claim will “assist consumers in maintaining healthy dietary practices.” 21 C.F.R. § 101.14(e)(3). In such cases, FDA requires a disclosure statement about the nutrient that exceeds the disqualifying level (*e.g.*, “see nutrition information for fat content”). FDA has exercised this authority with respect to certain health claims. For example, the health claim for plant sterol/stanol esters and risk of coronary heart disease (CHD) provides that spreads and salad dressings bearing this health claim may exceed the disqualifying level for total fat content per 50 grams (g) or product. 21 C.F.R. § 101.83(c)(2)(iii)(C). Similarly, the qualified health claim for walnuts and risk of CHD provides that whole or chopped walnuts bearing this claim may exceed the disqualifying level for total fat. FDA, Letter of Enforcement Discretion – Walnuts and Coronary Heart Disease (March 9, 2004).

The proposed rule would set out the factors the agency will consider in determining whether to grant such an exemption. The proposed factors are:

- The public health significance of the risk of the disease or health-related condition that is the subject of the claim and the role that diet plays in decreasing that risk;
- The availability of foods that qualify to bear the health claim;
- Evidence showing that the population to which the health claim is targeted is not at risk of the disease or health-related condition associated with the disqualifying nutrient (and the ability of individuals to identify themselves as being at risk for the disease or health-related condition associated with the disqualifying nutrient); and
- All other evidence showing the public health need for waiving the disqualification requirement.

NCA and CMA believe this list of factors is appropriate and commend FDA for making these determinations more transparent.

We believe that FDA should go a step further and revise the disqualifying levels themselves. In particular, the disqualifying level for total fat is no longer consistent with dietary recommendations. A disqualifying level is only appropriate if there is scientific consensus that a nutrient above a specific level of intake increases the risk of a diet-related disease to the general population. While such a consensus existed for total fat in 1993, it no longer does.<sup>2</sup> According to the National Academy of Sciences' Institute of Medicine (IOM), "there are insufficient data to determine a defined level of fat intake at which risk of inadequacy or prevention of chronic disease occurs."<sup>3</sup> Consequently, the IOM has set an Acceptable Macronutrient Distribution Range (AMDR) for total fat -- 20 to 35 percent of energy for adults -- but has not established a Recommended Dietary Allowance (RDA) or Tolerable Upper Intake Limit (UL).<sup>4</sup> Similarly, the 2005 edition of the *Dietary Guidelines for Americans* recommends total fat intake for adults within a range of 20 to 35 percent of calories and emphasizes reduced intake of specific lipids (*i.e.*, saturated fat, *trans* fat, and cholesterol) rather than of fat in general.<sup>5</sup> FDA itself has noted a "change in expert opinion on total fat intake" and the risk of heart disease, stating that "current scientific evidence does not indicate that diets high in unsaturated fat are associated with CHD." 65 Fed. Reg. 54686, 54710 (Sept. 8, 2000). NCA and CMA believe FDA's regulations should be amended to reflect the new consensus by removing the disqualifying level for total fat.

We also suggest that foods should be permitted to subtract stearic acid from their saturated fat content for purposes of the saturated fat disqualifying level. There is considerable scientific evidence that stearic acid, a saturated fat, does not increase serum cholesterol levels and does not increase risk of CHD. According to the IOM, "dietary stearic acid has metabolic effects that are

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<sup>2</sup> Early editions of the *Dietary Guidelines for Americans* recommended a diet with total fat at 30 percent or less of total calories.

<sup>3</sup> IOM, *Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*, 2002 ("Macronutrient Report"), p. 8-1.

<sup>4</sup> A UL was not set for total fat because of "the lack of a defined intake level at which an adverse effect, such as obesity, can occur." IOM, *Macronutrient Report*, p. 8-47.

<sup>5</sup> The report of the Dietary Guidelines Advisory Committee made clear that reducing intake of specific fatty acids is more important than reducing overall fat intake. ("The main goals are to keep saturated fat intake below 10 percent of calories, *trans* fat intake below about 1 percent of calories, and cholesterol intake below 300 mg per day"). 2005 Report of the Dietary Guidelines Advisory Committee, p. 5. The report states that high fat intake increases risk of heart disease by increasing saturated fat intake. The disqualifying level for saturated fat addresses this concern.

closer to those of oleic acid rather than those of other long chain saturated fatty acids.”<sup>6</sup> If a particular nutrient does not increase the risk of a diet-related disease in the general population, it should not be the subject of a disqualifying level.

**2. The 10% nutrient contribution requirement should be revised to allow greater flexibility.**

A food may not bear a health claim unless it contains 10 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) for one of six nutrients (*i.e.*, vitamin A, vitamin C, iron, calcium, protein, or fiber) per reference amount prior to any nutrient addition. 21 C.F.R. § 101.14(e)(6). The purpose of the 10% minimum nutrient contribution requirement is to prevent use of health claims to promote consumption of foods that are incompatible with dietary recommendations.<sup>7</sup>

FDA is proposing to exempt certain foods, such as fruit and vegetable products composed solely of fruits and vegetables, from this requirement. NCA and CMA support this exemption and believe it should be extended to include fruit and vegetable products with added oils, sauces, syrups, sodium, and other ingredients. Many frozen, canned, and dried fruit and vegetable products contain small amounts of added ingredients. Exempting such products from the 10 percent nutrient contribution requirement would encourage increased consumption of fruit and vegetable products that are more convenient and more palatable to some consumers.<sup>8</sup> In addition, FDA has in the past exempted specific health claims (*e.g.*, the health claim for noncariogenic carbohydrate sweeteners and dental caries) from the 10 percent nutrient contribution requirement where there is a public health need to promote consumption of foods that are unable to meet this requirement. 21 C.F.R. § 101.80(c)(1).

CMA and NCA believe that, in addition to carving out exceptions, the 10 percent nutrient contribution requirement should be revised to allow greater flexibility. First, the list of nutrients that can be counted to meet this requirement should be expanded. The 2005 edition of the *Dietary Guidelines* notes that there is a need to increase Americans’ intake of other nutrients, including

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<sup>6</sup> IOM, *Macronutrient Report*, p. 8-8.

<sup>7</sup> While we question whether it is possible to make such a clear distinction between foods that are consistent with dietary recommendations and those that are not, NCA and CMA are not requesting that FDA eliminate the 10 percent nutrient contribution requirement at this time.

<sup>8</sup> The *Dietary Guidelines* make clear that most Americans need to increase their consumption of fruits and vegetables. *Dietary Guidelines for Americans, 2005*, Figure 1.

vitamin E, magnesium, potassium, and folic acid.<sup>9</sup> Where inadequate intakes of a nutrient are a public health concern, foods containing that nutrient should satisfy the 10 percent nutrient contribution requirement. FDA should be willing to consider expanding the list of nutrients further as science and public health needs evolve. In addition, it should be possible to cumulate nutrients for purposes of meeting the 10 percent requirement. For example, a food that contains 5 percent of the RDI for calcium and 5 percent of the DRV for fiber prior to any nutrient addition should satisfy the requirement.

**3. FDA should permit abbreviated health claims without requiring that the complete claim appear elsewhere on the label.**

NCA and CMA believe that the lengthy, complex wording of many health claims discourages companies from using the claims and consumers from reading them. While label space may be precious to manufacturers, it is not nearly as precious as time is to the consumer reading the label. A verbose health claim is likely to be glossed over, if it is noticed at all.

The proposed rule would address this long-standing problem in two ways: (a) by making certain mandatory elements (*e.g.*, a statement about the multi-factorial nature of the disease or health-related condition) optional; and (b) by allowing abbreviated health claims. An abbreviated claim would consist of “a truthful, non-misleading, and scientifically valid description of the relationship between the substance and the disease or health-related condition.” NCA and CMA believe that both reforms are needed.

Consumers generally understand that there are many risk factors for every disease. A statement that a particular disease has many risk factors, therefore, is stating the obvious. Recognizing this, the health claims approved by FDA more recently do not require this element, provided the claim does not imply that consumption of a particular substance is the only recognized risk factor.

NCA and CMA also strongly support FDA’s proposal to allow abbreviated health claims. Most health claims are verbose and not consistent with the design of the principal display panel of most food products. An abbreviated health claim that clearly and succinctly states the substance-disease relationship would be an incentive to greater use of health claims. We do not think that the proposed shortening of certain health claims by removing some required elements would make this issue moot. Even with such shortening, the need for abbreviated health claims will remain. For

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<sup>9</sup> According to the Dietary Guidelines Advisory Committee report, “... efforts are warranted to promote increased dietary intakes of vitamin E, calcium, magnesium, potassium, and fiber by children and adults.... Adolescent female and women of childbearing age need extra iron and folic acid.”. 2005 Report of the Dietary Guidelines Advisory Committee, p. 3

example, the health claim for sugar alcohols and reduced risk of dental caries is quite wordy and would not be shortened under the proposed rule. The model health claims in FDA's regulation range from 25 to 35 words in length. A shortened claim is allowed only for use on packages with less than 15 square inches of available label space. 21 C.F.R. § 101.80(c)(2)(G), (e).

NCA and CMA believe, however, that an abbreviated health claim should be permitted to stand alone. The complete health claim should not be required to appear elsewhere on the label. If an abbreviated health claim is a truthful, non-misleading, and scientifically valid description of the substance-disease relationship, it should not require further elaboration. As previously noted, confectionery products generally have very limited label space. For products with limited label space, it may not be possible to use abbreviated health claims if they must be accompanied by a referral statement and the complete health claim elsewhere on the label.

**4. FDA should no longer require use of the word “may” or “might” in health claims.**

FDA has requested comments on whether health claims should continue to require use of the word “may” or “might” to indicate the multi-factorial nature of the disease referred to in the claim. FDA expressed concern that consumers may misinterpret the word “may” or “might” to mean that the scientific evidence supporting the claim is inconclusive.

We share FDA's concern. Especially now that FDA has begun to authorize qualified health claims, the requirement to use the word “may” or “might” in unqualified health claims blurs the distinction between the two categories of health claims. Moreover, the word “may” or “might” is no longer necessary to inform consumers of the multi-factorial nature of disease. As noted above, we believe that consumers understand that every disease has many risk factors and that dietary practices alone cannot guarantee that one will not develop a particular disease.

Both the requirement to use the word “may” or “might” and the required statement about the multi-factorial nature of disease may be safely removed from FDA's regulations. Provided a health claim does not imply that consumption or avoidance of a particular substance is the only recognized risk factor, these required elements are not needed to inform consumers of multiple risk factors.

**5. FDA should allow use of unlisted synonyms for authorized nutrient content claims, but the “anchoring” approach discussed in the proposed rule is too confining.**

NCA and CMA support FDA's proposal to allow use of unlisted synonyms for nutrient content claims. Authorization of unlisted synonyms would allow greater creativity in marketing nutritionally improved foods to consumers. By establishing clear standards for the use of unlisted synonyms, the proposed rule would provide a level playing field and prevent consumer confusion. NCA and CMA urge FDA to finalize this proposed amendment.

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We question, however, the need for the “anchoring” approach proposed by FDA. If an unlisted synonym is “reasonably understood by consumers” to be a synonym for a defined nutrient content claim or a listed synonym, we do not see why it should be necessary to “anchor” the unlisted synonym to the defined term or listed synonym. Most consumers are not aware of the distinction between defined terms, listed synonyms, and unlisted synonyms. As long as the unlisted synonym is understood by consumers to be a synonym for the defined claim, one or the other should make the point quite clearly. For example, a claim of “minus the sugar” would be reasonably understood by consumers to be a synonym for the defined nutrient content claim “sugar free.” As long as the defined claim or a listed synonym (*e.g.*, “no sugar”) appears prominently and conspicuously on the product label, we do not believe it is necessary to have highly prescriptive label placement and type size requirements. We therefore suggest that proposed § 101.13(r)(2)(ii) be revised to require only that the defined term or listed synonym must appear “prominently and conspicuously on the label”; the remainder of this subsection should be deleted.

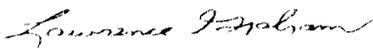
The “anchoring” approach proposed by FDA would act as a disincentive for confectionery products, many of which have very limited label space, to use unlisted synonyms. If FDA believes that an unlisted synonym is being used in a misleading manner, FDA has authority to take enforcement action under the general prohibition against false or misleading labeling (21 U.S.C. § 343(a)).

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We appreciate this opportunity to comment.

Respectfully submitted,

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