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**June 17, 2005**

**BY ELECTRONIC MAIL**

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

Re: Docket Nos. 2004N-0463 and 2004N-0456

The National Confectioners Association (NCA) and the Chocolate Manufacturers Association (CMA) are pleased to have the opportunity to submit these comments on the Food and Drug Administration's (FDA) advance notices of proposed rulemaking (ANPRM) on possible label changes to facilitate weight management. Obesity in the United States is a serious health concern and NCA appreciates the opportunity to work with FDA to find ways to help consumers make appropriate dietary choices for their individual life styles.

NCA is the not-for-profit trade association representing more than 700 confectionery manufacturers, suppliers and brokers throughout the United States and internationally. CMA is the not-for-profit trade association representing the majority of chocolate manufacturers in the United States. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture a wide variety of finished chocolate and chocolate-containing confectionery products for the consumer market.

NCA and CMA support FDA's decision to reexamine the nutrition label in light of changes in Federal dietary guidance and food consumption patterns. At the same time, we believe FDA should proceed cautiously in changing a nutrition label that has, on the whole, served its purpose (*i.e.*, informing consumers about the important nutritional characteristics of food products) very well. We do not believe that the nutrition label is the cause of the current obesity epidemic, and we believe that FDA should not have unrealistic expectations about the ability of nutrition labeling alone to solve this public health problem. Any changes to the food label should be tested with consumers to validate the usefulness of the change, specifically with regard to weight control.

Our specific comments on the two ANPRMs follow.



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## **PROMINENCE OF CALORIES**

NCA and CMA agree with the Obesity Working Group's recommendation to increase the prominence of the Calories declaration in Nutrition Facts. However, we recommend that this be done in a way that does not compromise other goals of the nutrition label.

### **1. NCA and CMA support removal of the Calories from Fat declaration.**

NCA and CMA recommend that FDA delete the Calories from Fat declaration in Nutrition Facts. Calories, not calories from fat, is the critical piece of information that consumers need to manage their weight. Removal of the Calories from Fat declaration would have the effect of increasing the prominence of the Calories declaration. Without the Calories from Fat declaration, the Calories declaration would appear by itself on a separate line in the vertical display option for Nutrition Facts. If the tabular display option is used, the space previously occupied by the Calories from Fat declaration would be blank, accentuating the Calories declaration immediately above it.

The Calories from Fat declaration is unnecessary. The declaration for Total Fat already includes a Percent Daily Value (% DV) declaration, which helps consumers understand the significance of the amount of total fat in a serving of the product in the context of a daily diet. The Calories from Fat declaration is therefore redundant. We are not aware of any consumer research suggesting that consumers regularly use this information.<sup>1</sup>

Singling out total fat as the only nutrient requiring three declarations (*i.e.*, amount in grams, % DV, and amount in calories) emphasizes total fat in a way that is inconsistent with the federal government's most recent nutrition advice. Recent editions of the *Dietary Guidelines for Americans* have emphasized reducing certain types of fat, saturated fat and *trans* fat, rather than total fat. They have also recognized that certain fats, such as omega-3 fatty acids, may have health benefits. In this light, the Calories from Fat declaration places undue emphasis on total fat. Consumers do not need this information to follow the government's official dietary guidance.

### **2. NCA and CMA would not object to additional minimal changes that enhance the Calories declaration.**

We believe the removal of the Calories from Fat declaration would, by itself, be sufficient to highlight the Calories declaration. In the absence of consumer research to support positive behavior change, we do not think the other changes discussed in FDA's ANPRM are necessary and offer the following comments.

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<sup>1</sup> In fact, most consumer research indicates that consumers prefer simplicity. *See, e.g.,* Lewis, CJ and EA Yetley, Focus Group Sessions on Formats on Nutrition Labels, *J. Am. Dietetic Assoc.* 1992. 92(1):62-66. Providing two information items that serve the same purpose arguably may confuse consumers.



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- a. **FDA should respect the advantages of uniformity in the Nutrition Facts Panel and not require mandatory change to the type size or style of the Calories declaration.**

Nutrition Facts was designed to use a uniform type size (except for headings and footnotes) and a uniform type style for a reason. Uniformity in type size and type style is visually appealing and attracts the consumer's eye to this part of the label. Uniformity also makes Nutrition Facts easier to read. We think any departure from uniformity of type size and type style would risk losing these important benefits, especially for individuals whose main concern is not weight control – but may instead be sodium, saturated fat or fiber intake, for example.

While we do not support altering the type style, if FDA believes that further modifications are needed to accentuate the Calories declaration, **NCA and CMA would support voluntary approaches to increase the prominence of calories through guidance from FDA such as accentuating the word “Calories” in extra bold type.**

If FDA decides on a mandatory approach to increase the type size of the Calories declaration, we hope the increase would be small and that FDA will be cognizant of the impact of any such increase on label space, especially for products like confectionery that are often sold in small packages. In addition, we would prefer that any increase in type size be voluntary.

Alternatively, if any item in Nutrition Facts is to be increased in type size or style, we suggest that it be the Servings Per Container declaration. This declaration alerts consumers when the nutrition information in Nutrition Facts does not apply to the entire container.

- b. **FDA should not require a % DV declaration for Calories.**

NCA and CMA also oppose a % DV declaration for calories. We believe that a % DV declaration would, like the current Calories from Fat declaration, distract attention from the Calories declaration itself. Adding a % DV declaration for calories would therefore defeat the main purpose of deleting the Calories from Fat declaration.

Requiring a % DV for calories also would not provide consumers with useful information. An individual's calorie needs are highly individualized and variable. According to the U.S. Department of Agriculture's (USDA) MyPyramid, calorie needs depend upon an individual's age, sex, and physical activity level. A particular individual's daily calorie needs vary depending upon his or her caloric expenditure on the day in question. Requiring a % DV declaration for calories based on a one-size-fits-all (2,000 calorie/day) approach would be inconsistent with MyPyramid, which advises consumers to ascertain their individual caloric requirement, and would confuse consumers. This would be especially detrimental for women and children whose daily caloric needs may be less than 2,000 calories. If FDA



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and USDA are encouraging consumers to be more aware of their individual calorie needs, it makes little sense to require a % DV declaration for calories based on a 2,000-calorie diet.

**c. FDA should not require a declaration of calories per serving or per package on the principal display panel.**

NCA and CMA strongly oppose any requirement to present calorie information on the principal display panel (PDP) of the label. It is important that all mandatory nutrition information be presented in one location on the label, the Nutrition Facts panel. Scattering nutrition information throughout the label inevitably would distract attention from Nutrition Facts. It might lead some consumers to think they must now read both the PDP and the information panel to find complete nutrition information about a product, a time-consuming task that few consumers would undertake. While nutrition-related claims and factual statements about nutrient content may already voluntarily appear on the PDP, requiring mandatory nutrition information to appear anywhere outside the Nutrition Facts panel would set a dangerous precedent.

We also question whether requiring calorie information on the PDP would accomplish FDA's intended purpose. The PDPs of most food products are already cluttered. In addition to mandatory label information required to appear on the PDP by FDA regulation (*e.g.*, the statement of identity, net contents declaration, and information about the charactering flavor if any), the PDP also must contain a variety of other information (*e.g.*, the product's brand name, trademarks, kosher labeling) as a matter of business practice and consumer expectation. Calorie information appearing on the PDP might not be noticed or read by consumers.

Calorie information on the PDP might also be misunderstood by consumers. If calorie information *per serving* is presented on the PDP, this might be misinterpreted by some consumers to mean that the entire package contains the number of calories declared. Even if the statement declares "x calories per serving," some consumers might overlook the words "per serving." On the other hand, if calorie information *per package* is presented on the PDP, this might be interpreted by some consumers as permission to consume the entire package.

## **SERVING SIZES AND REFERENCE AMOUNTS**

### **1. FDA should take a conservative approach to updating reference amounts.**

NCA and CMA recommend FDA to take a conservative approach to updating of the reference amounts customarily consumed (RACCs) listed in 21 C.F.R. § 101.12(b), tables 1 and 2. NCA and CMA are concerned that some RACCs would be increased and that increased RACCs will translate into increased serving sizes and more calories per serving. The inherent risk is that consumers will view increased serving sizes as a license to eat more. We doubt there is any way that FDA can avoid the



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implication that the serving size declared on the label is, in some sense, a recommended serving. Therefore, we suggest that RACCs be updated only if recent consumption data demonstrate that existing RACCs are clearly outdated and inconsistent with average portion sizes.

NCA and CMA request that FDA revise the RACCs for confectionery products to add the following product categories:

| <u>Product Category</u>  | <u>RACC</u> |
|--|-------------|
| o Chocolate-covered fondants ( <i>e.g.</i> , chocolate-covered creams, chocolate-covered mints), taffy, and plain toffee             | 30 g        |
| o Hard candies, others; after-dinner mints, caramels, fondants ( <i>e.g.</i> , plain mints, candy corn), liquid and powdered candies | 15 mL/15 g  |

These product categories and reference amounts were set forth in a 1998 proposed rule that was withdrawn by FDA last year.<sup>2</sup> We believe the withdrawal was based on FDA's commitment of limited resources to other priorities and was not the result of a change in FDA's position. The candy industry would like to have these RACCs codified. We believe that adding these product categories and RACCs is consistent with the purpose of this rulemaking (*i.e.*, reducing obesity by reducing portion sizes) and is consistent with the way consumers eat confections.

**2. NCA and CMA support increasing the prominence of Servings Per Container declared in the Nutrition Facts for packages that can reasonably be consumed at one eating occasion rather than a requirement that such packages be labeled as a single serving.**

We do not support a requirement that all packages that can reasonably be consumed at one eating occasion must be labeled as a single serving. This requirement would be very difficult to enforce, since it calls for a very subjective determination (*i.e.*, whether a particular amount of food can reasonably be consumed at one eating occasion). Different manufacturers might reach different conclusions regarding the same amount of product. Alternatively, FDA would have to set this amount for each food product category, a questionable use of FDA's limited resources.

Labeling large packages as single servings might be counter-productive and construed by some consumers as giving them permission to eat the entire package. It is not possible for FDA to prevent some consumers from making the inference that the serving size, however large, is a recommended portion size.

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<sup>2</sup> See 63 Fed. Reg. 1078 (Jan. 8, 1998) (proposed rule) and 69 Fed. Reg. 68831 (Nov. 26, 2004) (notice of withdrawal).



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Rather than altering the existing rules for determining serving size, NCA and CMA believe that FDA's purpose can be achieved by increasing the prominence of the Servings Per Container declaration in Nutrition Facts. As we understand it, FDA is concerned that consumers who do not read the Nutrition Facts panel carefully may mistakenly believe that the nutrition information on the label of a multi-serving package applies to the entire package. When a consumer picks up a package of food, his or her default assumption is that the entire package constitutes one serving, unless contrary information is provided. We agree that the nutrition label should not be a trap for the unwary. Logically, the best way to inform consumers that a package contains more than one serving is to highlight the Servings Per Container declaration on multi-serving packages.<sup>3</sup> If the consumer is made aware that the package contains more than one serving, he or she can make the simple calculations needed to arrive at the nutrient values for the entire container. For single serving containers, there is no need to highlight serving information, because the entire package constitutes one serving.

### **3. FDA should permit comparative claims for smaller portions of the same food.**

NCA and CMA support authorization of comparative calorie claims comparing different portion sizes of the same food. We believe this would encourage manufacturers to produce, and consumers to purchase, smaller portion sizes. Such comparative claims should be allowed to use defined terms (*e.g.*, "fewer calories"), provided such use is not false or misleading. When comparing different portion sizes of the same food, claims should not be permitted to use terms that might suggest a difference in formulation (*e.g.*, "reduced calorie"). This is an example of an area where consumer testing is crucial to validate the usefulness and understanding of these claims to assure that such claims are not misleading to the consumer.

Such claims should be required to include the identity of the reference food and the percentage (or fraction) reduction in calories (*e.g.*, "30% fewer calories than our jumbo bar").<sup>4</sup> Provided the percentage (or fraction) difference in calories is stated in the claim, FDA should not require any minimum caloric reduction. Like all relative claims, quantitative information comparing the number of calories in the labeled food and the reference food should be required to appear on the information panel.

Comparative calorie claims should not be limited to products that are identical. We see no reason why manufacturers should not be permitted to make a claim comparing the calorie content of a 5-ounce milk chocolate bar to that of a 10-ounce dark chocolate bar, provided the claim is not false or misleading.

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<sup>3</sup> The Servings Per Container declaration could be highlighted by use of bold type or other means. As discussed above, we support maintaining the uniform type size and type style for information in the Nutrition Facts panel.

<sup>4</sup> Such claims should be allowed to identify portion sizes in general terms (*e.g.*, "jumbo bar" in lieu of "6 ounce bar").



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**GENERAL COMMENTS**

NCA and CMA urge FDA to consolidate all changes to Nutrition Facts into one “rulemaking package” with a single compliance date. The changes being considered in these two ANPRMs and other planned rulemakings (e.g., revision of the Daily Reference Values (DRVs) and Reference Daily Intakes (RDIs) to reflect the new Dietary Reference Intakes issued by the Institute of Medicine) would require changing the label of virtually every food product sold in the United States. The food industry is now in the process of changing the labels of a large percentage of their products to comply with FDA’s *trans* fat labeling rule and the new allergen labeling requirements set forth in the Food Allergen Labeling and Consumer Protection Act of 2004. The food industry should not be expected to re-label all of their products every two years. Doing so would be very expensive, with costs likely passed on to consumers, and would effectively force companies to discontinue offering small brands, which would simply not be worth the continuing costs or re-labeling.

We request that FDA time all of the label changes contemplated in these two ANPRMs, as well as other planned label changes that will have a widespread impact, to have the same compliance date. The compliance date chosen should give industry sufficient time to comply, bearing in mind that compliance will require re-labeling virtually every food product.

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NCA and CMA appreciate this opportunity to share our views with FDA on these rulemakings.

Respectfully submitted,

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