June 20, 2005

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

Re: **Docket No. 2004N-0463: Food Labeling; Prominence of Calorie (April 4, 2005)**
Docket No. 2004N-0456: Food Labeling: Serving Sizes of Products that can Reasonably be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes (April 4, 2005)

Dear Sir or Madam:

The Snack Food Association (SFA) appreciates this opportunity to offer comments concerning the above-referenced Food and Drug Administration (FDA) Advance Notices of Proposed Rulemaking (ANPRs). The Snack Food Association is an international trade association representing snack food manufacturers and suppliers. SFA membership includes smaller regionally based snack food companies in addition to large national branded snack food manufacturers. Retail sales of snack foods in the U.S. total more than $30 billion annually.

SFA applauds FDA's efforts to consider possible approaches that may assist consumers in maintaining healthy dietary practices. The agency should not, however, assume that regulatory options are necessary or will provide "the answer" to the complex issues of calorie control and weight management. Given the substantial cost of label changes, especially to smaller businesses, we urge FDA to not propose changes to the well-established and familiar Nutrition Facts format or serving size information absent sound research and clear evidence of a meaningful benefit to consumers.

PROMINENCE OF CALORIE LABELING

For more than a decade, the Nutrition Facts panel has provided nutrition information for American consumers in a prominent and uniform format. FDA research suggests that consumers are familiar with the Nutrition Facts panel, which includes calorie information as a major feature. SFA is aware of no research or other information suggesting that consumers do not know how to locate calorie information in food labeling, nor does FDA cite any such research. Accordingly, the benefits of possible requirements suggested by FDA, such as providing calorie information on the front panel or other label adjustments (e.g., increasing the font size of calorie declarations) are unclear. The concept of a percent DV for calories seems particularly troubling, given the evidence suggesting that consumers do not fully understand or use daily values in food labeling.

Before the possibility of additional or revised nutrition labeling requirements may be reasonably explored, SFA suggests that several preliminary steps are necessary. First, as FDA suggests, information concerning actual consumer use of the food label is needed. Before labeling changes may be considered or effective educational efforts can be developed, a sound understanding of the consumer perspective is essential.

Second, once consumer practices are better understood, SFA believes that thought must be given to development of effective consumer education programs. If, as FDA research suggests, consumers are not using the Nutrition Facts panel for weight control purposes, why is this the case? Is it an issue of design or formatting, or does it reflect a need for nutritional counseling regarding dietary strategies for weight loss which a label cannot reasonably provide even under the best of circumstances? SFA strongly supports consumer nutrition education as a valuable and meaningful undertaking and urges FDA to consider increased use and study of nutrition education as a strategy for achieving weight maintenance or loss.

Third, the impact of voluntary measures currently used by industry should be assessed. For example, many of SFA's member companies are voluntarily making strides in assisting consumers with portion control for snack products. Several members recently introduced calorie-controlled snack packs (e.g., 100 calorie packs), which is one of a few strategies that the snack food industry is using to meet the demand for products that fit into consumer diets.

In summary, SFA suggests that FDA not pursue mandatory regulations prematurely, especially without the benefit of further study into consumer use of existing labeling, the effect of education on consumer use of labeling, and the effects of voluntary industry measures.

SERVING SIZES

SFA also urges FDA to proceed with caution as the agency evaluates the need for changes to the existing reference amounts customarily consumed (RACCs), which form the basis for serving sizes used in nutrition labeling. SFA is particularly concerned that widespread changes in RACCs and resulting changes in serving size could confuse consumers (e.g., by making them think a product formulation or other attribute has changed, when that is not the case, or by making them think more of a food should be consumed, if serving sizes increase) and add substantial costs for re-labeling. Further, revising the RACCs, arguably the most difficult area of the Nutrition Labeling and Education Act (NLEA) for FDA to implement, would divert significant agency resources from other, more useful, pursuits. SFA suggests that the existing RACCs are adequate and should not be revised absent a specific and compelling need.

FDA specifically asks whether the agency should reconsider the meaning of "serving size," which NLEA defines as an amount "customarily consumed." As SFA understands it, the impetus for this question is data suggesting that consumers (1) are eating larger portion sizes than they have in the past, and (2) understand the serving size to be an amount recommended for consumption. In the 1993 rulemaking to implement NLEA, FDA interpreted the statute to require serving sizes to be based on statistical measures of actual consumption data (i.e., means, medians, and modes); if FDA were to take the same approach now, serving sizes might increase. FDA expresses concern that increased serving sizes might lead consumers to believe that they can or should eat larger amounts of food, which would hinder efforts to encourage moderate intake for weight control and maintenance.

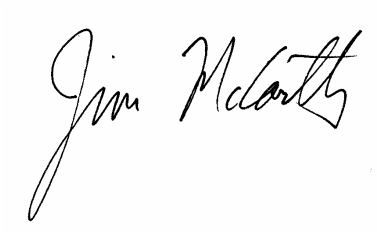
SFA shares FDA's concern. We believe that this concern is best addressed by interpreting the statutory standard of "customary" consumption to permit FDA to base RACCs and serving sizes on amounts reasonably recommended for consumption, taking into account actual consumption patterns, dietary guidance, common household measures, and other appropriate factors. The plain language of the statute does not mandate that serving sizes be based on actual consumption data, nor is such an approach consistent with the NLEA if it leads consumers to increase portion sizes inadvertently. FDA should not read into the statute a requirement to establish RACCs in a rigid manner that does not promote public health. SFA further believes that the existing RACCs, which were established prior to the present concerns about obesity, are presumptively reasonable and thus represent amounts "customarily" consumed. Accordingly, if FDA interprets "customary" consumption to reflect amounts reasonably or realistically consumed in the manner suggested, there is no need to revise the RACCs as a general matter.

EFFECT OF CHANGES MUST BE EVALUATED

Prior to exploring new or revised nutrition labeling requirements, FDA should, in addition to the considerations detailed above, carefully consider the effects of changes in labeling requirements on both consumers and the regulated industry. SFA is particularly concerned that revised requirements of the type described in the ANPRs will subject the snack food industry to successive changes in food labeling in a short period of time, resulting in substantial costs without clear evidence (to date) of meaningful benefits. SFA further believes that such multiple changes to the label could confuse the consumer.

SFA is committed to the development of FDA food labeling policy that enhances consumer understanding of current recommendations for healthful dietary practices. SFA looks forward to working with the FDA on these labeling issues and would be pleased to discuss any of the points made in these comments.

Sincerely,



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