June 20, 2005

Division of Dockets Management (HFA-305)
FDA
5630 Fishers Lane
Room 1061
Rockville MD 20852


Dear Sir/Madam:

The American Society for Clinical Nutrition, Inc. (ASCN) is pleased to comment on 21 CFR Part 101: Food Labeling; Serving Sizes of Products that can Reasonably be Consumed at one Eating Occasion, etc. ASCN found this to be an extensive and comprehensive document and commends the FDA staff for the clarity of the document given the breadth of scientific issues included.

Background/Rationale for ASCN Comments:

In January of 2005, the Institute of Medicine (IOM) published an action plan on childhood obesity, Preventing Childhood Obesity: Health in the Balance, in which it is stated: “Research has revealed a progressive increase, from 1977 to 1998, in the portion sizes of many types of foods and beverages available to Americans (Nielsen and Popkin, 2003; Smiciklas-Wright et al, 2003) and the concurrent rise in obesity prevalence has been noted (Nestle, 2003; Rolls, 2003).” This IOM report as well as that of the FDA Obesity Working Group (OWG), Calories Count, acknowledges a trend toward eating more beverages, snacks and meals in which large portion sizes are increasingly common. It appears that what can reasonably be consumed at one eating occasion is being shaped by the size of portions offered by food manufacturers and sold in grocery stores and other retail outlets. A similar trend toward increased size of portions offered in restaurants and fast food establishments is shaping the amount of food consumers expect to be offered when dining out.

It might reasonably be asked if larger portions lead to increased food consumption and the evidence presented in the IOM report on childhood obesity suggests that it does. The published research of Barbara Rolls and Leann Birch cited in the report support the assertion that children are being offered larger portion sizes and that larger portion sizes induce greater food intake in children as young as five. Similar data have been published in adults. The IOM report discusses the many factors that are contributing to the dramatic tripling in obesity
prevalence among U.S. children and teens. The following comments are written from the perspective that it is imperative that we stem the obesity epidemic and that the needs of children, teens and their parents or caregivers should be of paramount importance as changes to the Product Display Panel (PDF) and Nutrition Facts Panel (NFP) are considered.

The NFP is inherently educational, but qualitative research described in the FDA report, Calories Count, suggests that the serving size information has been confusing to many consumers. Providing consumers with gender and age specific information on their calorie needs might help them control their serving sizes. To accomplish this, ASCN recommends that FDA direct consumers to a website that is identified on the food label, such as www.mypyramid.gov, which offers a mechanism for providing personalized information to consumers on the role of calories in weight management. The consumer interested in weight management needs to understand his or her own estimated calorie needs in order to appreciate the calorie contribution of a given product relative to those needs. We recommend that this website URL appear on product food labels.

In this Advanced Notice of Proposed Rulemaking (ANPR), the FDA has requested comments on a series of questions addressing four topics related to calorie information on food labels:

**Topic 1:** the differentiation for consumers between serving sizes on the NFP and a recommended portion size;

**Topic 2:** an approach for updating the reference amounts customarily consumed per eating occasion (RACCs);

**Topic 3:** single-serving containers; and

**Topic 4:** comparison of calories in foods of different portion sizes.

ASCN’s responses to these topics are:

**Topic 1:** FDA’s focus group research suggests that consumers erroneously understand the serving size as equivalent to a recommended portion size. Also, the serving size information is often not readily useful to the consumer as a standardized unit of measure. For example, the size of a single serving of cereal in a standard box as presented in ounces is difficult for an individual to visualize, and when accurately measured by an individual in the home may be so small as to appear inconsequential. In contrast, a serving size of 13 potato chips may seem extravagant for a person trying to count calories, while a serving size of 0.5 cookies may be unrealistic. ASCN recommends that the serving size be made more realistic for consumers by 1) using units of measurement that are more readily understood by the consumer, such as teaspoons and cups; and 2) requiring that portion sizes be expressed in terms of US government recommendations for healthy eating as found in the HHS/USDA Dietary Guidelines for Americans 2005 and the USDA Food Guide Pyramid.

**Topic 2:** ASCN concurs that using the current RACCs, which are based on portion size data from the 1970’s and 1980’s, results in NFP serving sizes that are not equivalent to American eating habits today. However, we are strongly against using more current data to establish updated portion sizes, particularly in light of the increased prevalence of obesity. Instead, ASCN strongly urges the FDA to consider harmonizing the serving
size on the NFP with the recommendations from the Dietary Guidelines for Americans 2005. These Dietary Guidelines represent the best current scientific consensus on the approach for the individual and family to healthy eating and physical activity. Such an approach to serving size on the NFP would not only underscore the importance of these carefully developed government recommendations, but also result in serving size units that are more understandable by the American public.

**Topic 3:** Consumers use information on food labels to evaluate single foods and to compare foods. In practice, this means that they use food labels to decide (1) whether or not to purchase a food product, (2) whether or not to purchase one food product over another, (3) whether or not to consume a given food product at a particular eating occasion, and (4) whether or not to consume one food product versus another that might also be available at a particular eating occasion. Our goal is to recommend actions that might be taken to inform children, teens and parents who are struggling to make purchasing decisions as well as decisions about what to eat and how much to eat for the purpose of weight management.

The size of the product serving size relative to a RACC is immaterial if there is a possibility that the entire product will be consumed at one eating occasion. In other words, since consumers treat food products – even large ones – as a single serving, we believe that the calorie information on products should be expressed with this consumer behavior in mind. Thus ASCN is calling for dual calorie labeling as explained below.

- Regardless of the size of the package or container, all food products marketed and sold to consumers should have calories listed on the NFP as calories per portion and also as calories per package.

- The font size for the calorie information should be large enough to be clear and legible and should be specified by the FDA; other restrictions may be needed to insure that the “calories per product” information is prominent, clear and non-misleading.

- Since the consumer may want to make product comparisons, or manufacturers may wish to encourage product comparisons, calorie information per recommended serving size should be listed on the PDP.

  (1) If calories in a product are related to a recommended serving size, that serving size should be consistent with the Dietary Guidelines for Americans 2005 and Food Guide Pyramid.

  (2) If used on a food product label, recommended serving sizes should be expressed in commonly used household measures such as calories per cup, per ½ cup, per tablespoon, etc.

  (3) Because they are confusing and require mental calculations that are too demanding for most consumers, fractions of a serving should not be permitted on food labels and manufacturers should be required to size their products to eliminate the need for fractions.

**Topic 4:** ASCN agrees with the OWG that allowing manufacturers to make “truthful, non-misleading label claims comparing foods” will help consumers with their purchasing and consumption decisions. Our goal is to make those comparisons based on calories easy to understand and act upon for the sake of weight management. However, ASCN reiterates its belief, voiced in a similar comment in response to the ANPR on label health claims in spring 2004, that current, well-designed, scientific data on consumer understanding and use of the
food label are lacking. Few data are available that quantitatively and qualitatively identify consumer understanding of nutrient content claims, structure function claims, or health claims alone or in relation to the information in the NFP. Further, there is no current demographic information on the use of the label, its impact on purchase decisions, or how the label helps consumers to compare food products and determine the contributions of a food product to an overall health-promoting diet. We again voice our concern that the FDA and USDA, as agencies responsible for food labeling, need the budgetary and staff strength to quickly amass a solid research base about consumer understanding and use of all aspects of food labels.

To ensure that the consumer is properly informed about the label changes once they occur, ASCN strongly recommends that any changes in food labeling be accompanied by a well-developed, timely, and multi-year consumer education campaign. Recent research has shown that consumers who are educated about the NFP rapidly understand the contents of the label and quickly incorporate its use into their food purchasing habits.

In conclusion, ASCN recommends that the FDA 1) collaborate with USDA to establish a website URL that appears on the food product label; 2) require that manufacturers place “calories per package” or “calories per container” prominently on the food label along with “calories per serving”; 3) use units of measurement that are more readily understood by the consumer, such as teaspoons and cups; 4) regulate portion sizes so that they are no longer driven by the RACC but are instead harmonized with the Dietary Guidelines/Food Guide Pyramid recommendations for healthy eating; 5) ensure that product labels are designed in such a way that the consumer realizes the difference between “calories per container” and “calories per recommended serving size”; 6) allow manufacturers to make “truthful, non-misleading label claims comparing foods” where the unit of comparison is the recommended serving size provided by the Dietary Guidelines/Food Guide Pyramid instead of the RACC; and 7) accompany any changes in food labeling by a well-developed, timely, and multi-year consumer education campaign.

ASCN appreciates the opportunity to comment on these issues and commends the FDA staff for an exceptionally well-written document.

Sincerely,

Samuel Klein
President

Cc: ASCN Public Affairs Committee Members
References:


