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Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

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*

In FDA's efforts to improve and enhance the food label, ADA urges the agency to consider ways to harmonize the label with recommended dietary guidance. It is our members' experience that many consumers are confused and often frustrated in reading the label and trying to make meaningful decisions. As the serving sizes of many foods have increased in the last few decades (such as muffins, bagels, cookies, beverages, and other products in fast food restaurants and the home) the meaning of an appropriate serving size becomes less clear.¹ Concerns about what a 'serving' constituted were reviewed in depth in developing the 2005 Dietary Guidelines and the accompanying My Pyramid Plan, so that portions were given volume or weight measures.

It is the position of the American Dietetic Association (ADA) that health promotion and disease prevention endeavors are the best strategies for reducing the current burden of chronic disease, which includes obesity. Dietetics professionals are actively involved in promoting optimal nutrition in community settings and they advocate for the inclusion of healthy eating, in addition to other health-promoting behaviors, in programs and policy initiatives at local, state, or federal levels.²

ADA requests that the Food and Drug Administration (FDA) consider our comments in the context of the above position statement, which we believe is supportive of the Nutrition Labeling and Education Act (NLEA) of 1990, and recognizes the responsibility of the FDA as stated in the NLEA, "*the Secretary of Health and Human Services shall carry out activities which educate consumers about (1) the availability of nutrition information in the label or labeling of food, and*

¹ Nielson SJ, Popkin BM. Patterns and trends in food portion sizes. *J Am Med Assoc* 2003;289:450-453.

² Hampl GS, Amderson JV, Mullis R. Position of the American Dietetic Association: The role of dietetics professionals in health promotion and disease prevention. *J Amer Diet Assoc.* 2002;102:1680-1687.

(2) *the importance of that information in maintaining healthy dietary practices.*³ ADA members are well qualified health professionals who can assist the Secretary in achieving the NLEA educational mandate.

The following comments suggest possible approaches that the FDA can take to provide the information that consumers need to balance their energy intake and consume the nutrients they need for healthy long-term living.

General Comments

In the Background of this notice, the FDA states that, “*The Federal Food, Drug and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535), together with FDA’s implementation regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of their daily diet.*” Therefore, the purpose of FDA’s regulations that establish standards to define serving size should be fully consonant with the intent of the law, which is to create a mechanism to provide information to consumers. The information on the food label should reflect national nutrition policy, and thus the larger system of guidance for healthy eating practices for Americans, including the *Dietary Guidelines for Americans*. It should also address the concerns identified by the FDA Obesity Working Group.

The FDA reference serving sizes for labels function as one component of a larger source of nutritional information—the Nutrition Facts Panel (NFP). As the FDA works to enhance and improve the NFP to make it more meaningful, relevant and useful to consumers in adopting food behaviors that prevent obesity and other nutrition-related threats to health, the FDA needs to revisit and consider all other label components— such items as formatting, nutrient content and health claims, and the dietary reference intakes (DRIs). A comprehensive and integrated approach to labels should be considered, and FDA should conduct additional consumer research to understand the impact of any proposed label changes on the public’s comprehension and ability to discern and choose healthier food products. Moreover, well designed, adequately funded and sustained consumer education campaign should accompany any label changes. Improvements in the label information, without education, will not bring about the diet behavioral changes so greatly needed.

Updating RACCs

Consumers have expressed confusion over the serving sizes needed to achieve food guidance recommendations. ADA carefully reviewed the serving sizes for common food items as defined by the RACCs, the MyPyramid Plan, the DASH diet, and the Exchange Lists published by the American Diabetes Association, Inc. and the American Dietetic Association. ADA understands that the FDA is also in the process of examining the 1999-2002 NHANES data to calculate the mean, median, mode and percentile distributions of foods consumed at a single eating occasion to determine whether the RACC’s should be updated to reflect larger portion sizes typically consumed. ADA believes that, at the very least, a public review of these data should be conducted before they are used to update the RACCs.

ADA does not support increasing the RACCs based on current consumption practices. To do so, particularly for foods which contribute to ‘discretionary’ calories, as described by the 2005 Dietary Guidelines for Americans, would be contrary to the intended use of the label. The label

³ Nutrition Labeling and Education Act (NLEA) of 1990 (Public Law 101-535); Accessed June 14, 2005. <http://thomas.loc.gov/cgi-bin/query/F?c101:6:./temp/~c101Y6lXbL:e1238>:

should be an educational tool that consumers can use to adopt healthier dietary practices. Consumers might interpret the larger serving sizes as official dietary guidance, particularly since we believe the labels are more likely to be read by consumers than dietary guidance. Moreover, some foods that typically would not be considered a 'good source' of a particular nutrient might qualify if the RACCs were to increase. This could lead inadvertently to a false or misleading food label.

ADA also does not support lowering serving sizes for healthy foods, such as many fruits, vegetables, milk, or fruit and vegetable juices, just because consumers currently under-consume them. If our recommendation is to decrease the serving size for less healthy foods, while increasing the serving size for foods meeting current dietary guidance, then more foods might meet the requirements for certain kinds of nutrient claims. This is an example of why labeling revisions need to be fully integrated and done collectively. RACCs, claims, and DRIs are intertwined, and the impact of changing any one label component on the other label components needs to be carefully considered.

FDA should reexamine the basis for determining serving sizes in light of Congress' intention that NLEA be a tool to promote healthy eating, rather than a reflection of current food consumption trends. In our comparison of the RACCs for selected foods to MyPyramid, ADA observed that most food serving sizes were harmonious, with the exception of bread items and nuts (see below). In this case, RACCs values tended to be consistently larger than MyPyramid. However, the MyPyramid was designed to recommend portions that would fulfill certain nutritional requirements within a food group. To resolve these discrepancies for consumers, ADA recommends that the number of MyPyramid portions be printed next to the serving size RACC on the label (e.g., for tortillas, one serving = 55 g (2 ounce-equivalents of MyPyramid grains)).

Food Item	RACC	MyPyramid Equivalents
Bread, slice	50 g	1 ounce (30 g)
Tortilla, flour	55 g	1 ounce (6 inch diam)
Breakfast cereals	1 c	1c
Lettuce (raw)	1.5 cups	2 cups
Milk	1 cup	1 cup
Juices	8 fl oz	8 fl oz
Egg	1 large	1
Nuts	1 oz	½ oz
Peanut butter	2 Tb	1Tb

Thus, ADA believes that the FDA should keep the current RACCs for the reference serving sizes and communicate how they fit with MyPyramid by including the cup or ounce equivalents of the food groups from MyPyramid. This approach provides a consistent food-based system to help consumers plan and consume a healthy diet, as well as achieve the objectives of the FDA Obesity Working Group.

Single-serving Containers

A dual column should be required for comparing food product that is designed as a single serving or that could reasonably be consumed in one eating occasion with the reference serving sizes (i.e. RACCs) and recommended amount of the food item (i.e. MyPyramid). ADA does not support using the dual column for supermarket or bulk sized packages, since research indicates that consumers do not consider the information realistic or applicable to typically consumption patterns.

An alternative approach would be to establish the 95th percentile of a food consumed at a single eating occasion, using the NHANES data which are currently been analyzed by the FDA. This 95th percentile value at the upper end of intake could be the threshold to define “supermarket packaging.”

Comparison of Calories in Foods of Different Portion Sizes

ADA does not support comparison claims of the same food packaged in different portion sizes. Comparisons should only be made among the RACCs as done currently, by the MyPyramid serving, and the amount in that package. The term ‘reduced’ should not be used in calorie claims for the same food item in a smaller package. For bulk food items, only the calories for the RACC, the calories in the MyPyramid serving, and the number of RACC servings as well as My Pyramid servings in the package should be allowed.

Customarily-consumed amounts of food are no longer consistent with a healthy lifestyle. ADA recommends that FDA consider the purpose of the label and harmonize reference food servings to complement dietary guidance, minimize consumer confusion, and promote label credibility. Because of current consumer confusion, which is likely to be compounded with the introduction of any label changes, ADA reemphasizes that consumer educational campaigns initiated by the FDA are to be well planned, adequately funded, sustained nutrition efforts that are staffed by knowledgeable food and nutrition professionals, including registered dietitians.

Please do not hesitate to call Dr. Mary Hager, Senior Manager, Regulatory Affairs for the American Dietetic Association, at (202) 775-8277 with any questions or requests for additional information.

/s/

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⁴ Members of the Task Force: Constance Geiger, Alison Kretzer, Allison Yates, Suzanne Murphy, and ADA staff, Mary Hager.