



August 17, 2005

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

Dear Sir or Madam:

Re: 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

By advance notice of proposed rulemaking ("ANPRM") published in the *Federal Register* of April 4, 2005 (70 FR 17008), the Food and Drug Administration ("FDA") has requested comments on whether to amend certain provisions of the agency's nutrition labeling regulations concerning serving size.

Juice Products Association ("JPA") is a trade association whose regular membership consists of 68 processor companies located throughout the United States, Canada, Europe, and South and Central America. Its regular members include major packers and distributors of a wide variety of fruit and vegetable juices, juice beverages and drinks. Its members also produce jams, jellies, fruit spreads and other fruit products. JPA represents a significant majority of the juice and juice beverage processors in the United States. JPA offers the following comments in response to FDA's request.

FDA's request for comments was, according to the ANPRM, prompted by recommendations contained in the final report of the Obesity Working Group ("OWG") created by the Commissioner of Food and Drugs in August 2003. That report focused on a "calories count" emphasis for FDA as a result of its conclusion that weight control is primarily a function of a balance between calories consumed and calories expended.

Among the several recommendations made by the OWG to FDA were that FDA solicit comments on (1) whether to require food packages that can reasonably be consumed at one eating occasion to declare the whole package as a single serving, (2) which, if any, of the reference

amounts customarily consumed per eating occasion ("RACCs") of food categories need to be updated, and (3) whether to provide for comparative calorie claims for smaller portions of identical foods.

JPA believes that answers to most of the questions posed in the ANPRM with respect to possible changes in the serving size regulations are speculative because further science based research is needed to obtain information with respect to consumer's perceptions and reactions to serving size information on food labels. As recognized in the ANPRM, the report of the OWG stated that while most consumers are familiar with the nutrition information on food labels, the percentage of consumers who use information on the nutrition facts panel productively for weight management purposes is low. As stated in the report:

Despite reports of a positive correlation between label use and certain positive dietary characteristics, the trend toward obesity has accelerated over the past decade. It may be that consumers do not take advantage of the available information on the food label to control their weight, perhaps because they do not appreciate how it could be used for weight management purposes or perhaps because they find it too hard to apply the available information to such purposes. In any case, it is clear that consumers would benefit if they were to pay more attention to and make better use of information, including calories, on food labels. Providing encouragement and making it as easy as possible for consumers to do so are worthy public health objectives.

The report's possible conclusions for the acceleration of the trend toward obesity over the past decade could also have included that, perhaps, those who are obese or overweight do not use, or simply ignore, the information presented in the nutrition facts panels of foods.

To that end, JPA is recommending that if, in fact, reference sizes are not customarily used for weight management, but only as a reference point, that the standardized amount of 8 ounces as a single serving for juices be maintained. Research conducted for the Nutrition Education and Labeling Act determined that 8 ounces was the upper mode of juice consumption, which set the standard at that time. In keeping the 8-ounce reference, consistency for comparison purposes between products can be made.

Both the ANPRM and the OWG report that prompted it recognize that the trend toward obesity has accelerated despite the presence on food labels of more information than was available a decade ago prior to the passage of the Nutrition Labeling and Education Act and FDA's implementing regulations. They also recognize that many consumers have used the information on the nutrition facts panels of foods for other positive dietary considerations. JPA submits that before FDA actually proposes changes to the current regulations based on any of the three questions suggested by the OWG with respect to serving sizes, the other recommendations of the OWG with respect to additional research and education should be pursued. It should be remembered that the serving size for the food is the first item that appears in the nutrition facts panel, without which the other information presented on the NFP would be virtually meaningless, and comparisons among foods virtually impossible.

Before FDA proposes any changes to the Reference Amount Customarily Consumed (RACC), additional studies to determine whether the RACCs have actually changed over time will

be required and the results of such studies will need to be analyzed by FDA, food industry participants and consumer groups to determine a course of action. For example, if the data gathered shows that consumers are consuming more than the amount recommended in the Dietary Guidelines or the applicable MyPyramid recommendations, this fact alone could suggest a cause for the continuing trend toward obesity, and might be a reason to reevaluate the use of RACCs to determine serving sizes. The reverse of this example is also of significance; that is, the recommended studies may also show that consumers are not consuming the amounts of certain foods (e.g., fruits and vegetables, including juices) suggested in the Dietary Guidelines and MyPyramid recommendations. In this case, a downward adjustment in the RACCs for these foods would be at odds with the information conveyed by those recommendations.¹ Research would also be required to determine consumers' understanding of what is meant by the serving size on the nutrition label.

Virtually all of the questions posed by the agency under the issue of single serving containers will also require further research to determine consumers' understanding of serving size information generally, as well as in the context of a container or package for an amount greater than the serving size containing nutrition information for the entire container or package. Any proposed change to the existing regulation should await the results of this research.

The OWG report indicated, based on FDA's recent qualitative focus group research, that study participants "reacted positively" to a test label that had two %DV columns on the NFP, containing the absolute quantities of macronutrients in each of the two columns. One column would display nutritional information for a specified serving size and one for the entire package, when the package could reasonably be consumed as one serving. It appears, preliminarily, and assuming sufficient space is available on the label of a product, that such an approach could provide more meaningful information to consumers for use in maintaining healthier eating habits.

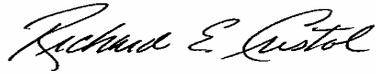
As previously indicated, the questions posed by FDA in the ANPRM require research to determine the answers. JPA supports FDA's conduct of the research suggested by those questions. JPA questions, however, whether changes to FDA's current labeling regulations can ever be effective in motivating consumers toward more healthful eating and drinking habits without a commitment by FDA and other government agencies to the educational efforts envisioned by the NLEA and recommended by the OWG report. A more consistent message between the 2005 Dietary Guidelines, the NFP and the message of individual responsibility conveyed by MyPyramid would be an example.

JPA appreciates the opportunity to comment on the important issues raised in the ANPRM.

¹ A complete departure from RACCs to determine serving sizes for purposes of nutrition labeling would require amendments to the Federal Food, Drug and Cosmetic Act but, as comments by other organizations in this docket have suggested, use of "an amount customarily consumed" in the applicable statute provides a certain amount of flexibility to FDA in determining serving sizes.

Division of Dockets Management (HFA-305)
August 17, 2005
Page 4

Respectfully,

A handwritten signature in black ink, reading "Richard E. Cristol". The signature is written in a cursive style with a large initial "R" and a long, sweeping underline.

Richard E. Cristol