January 4, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket Number FDA-2018-D-1459 titled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics: Guidance for Industry"

Dear Division of Dockets Management,

The Infant Nutrition Council of America (INCA) and the Healthcare Nutrition Council (HNC) are jointly responding to the notice published November 5, 2018 in the *Federal Register* by the U.S. Food and Drug Administration (FDA) entitled "Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion, Reference Amounts Customarily Consumed, Serving Size-Related Issues, Dual-Column Labeling, and Miscellaneous Topics: Guidance for Industry." INCA is an association of manufacturers of infant formula, follow-up formula, and growing up milks, whose member companies[1] produce over 95% of the infant formula consumed in the U.S. INCA advocates for optimal infant nutrition to ensure positive health outcomes, while supporting families in their feeding decisions and educating them on appropriate infant feeding options. HNC is an association representing manufacturers[2] of enteral nutrition formulas and oral nutrition supplements (ONS), parenteral nutritional formulas, supplies and equipment. HNC member companies are committed to improving health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. This includes promoting nutritional screenings, diagnoses, assessments and appropriate and timely nutrition interventions while protecting patients' access to specialized nutrition support products and services throughout the continuum of care.

INCA and HNC support FDA's efforts to update the Nutrition Facts label (NFL) and provide industry with needed guidance on Reference Amounts Customarily Consumed (RACCs). However, we are concerned with the answer provided in question B9 which indicates that non-juice beverages for children 1-3 years of age should follow the juice RACC of 4 fluid ounces (fl oz). This proposal would be a significant departure from current labeling practice for milk-based toddler drinks (products considered stage 3, follow-up formulas, and growing up milks) as well as Oral Nutrition Supplements (ONS) for children ages 1-3 years of age with differentiated health needs. These products play an important role in complementing the diet of this target group and are especially important in supporting growth, development, and overall health. These products are formulated with serving sizes greater than 4 fl oz to deliver specific calorie and protein levels uniquely designed to serve a purpose for the populations who use these products.

Up to this point, the common labeling practice has been to use other nutritionally comparable products (for example, milk or milk-based products rather than juice), consumption data, and practical consumer experience as the basis for determining the appropriate labeled serving size for milk-based toddler drinks and ONS products. The formula design for milk-based toddler drinks has thus been developed to provide appropriate nutrition in a different serving size (not usually 4 fl oz). Proposing an RACC via a guidance document with one year to comply leaves limited time to consider the need for reformulation, repackaging (e.g. scoop delivery), or re-labeling.

[1] INCA members are Abbott Nutrition, Gerber Products Company, Perrigo Nutritionals, and Reckitt Benckiser.
[2] HNC members are Abbott Nutrition, B. Braun Medical Inc., Nestle Healthcare Nutrition, and Nutricia North America.

As any FDA guidance on RACCs is significant, INCA and HNC recommend FDA proceed through formal public comment and rulemaking (such as that undertaken for developing or changing other product RACCs), rather than through regulatory guidance. This will provide transparency to the methodology used to establish the RACC and provide an opportunity for stakeholders to submit additional data for consideration. We welcome the opportunity to present our data and collaborate with FDA in advance of final rule making.

Thank you for the opportunity to provide comments. Please contact us with any questions you may have.

Sincerely,

Mardi K. Mountford, MPH
President, INCA

Nadia Cayce, PhD
Executive Director, HNC