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April 15, 2020

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

RE: Docket Number FDA-2018-D-1459-0049 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 January 2, 2020 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 (RACC), 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 (FUF), and growing up milks (GUM), whose member companies¹ 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 manufacturers² of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), parenteral nutritional (PN) 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 EN and PN products and services throughout the continuum of care.

The final guidance referenced above recommends that, for children ages 1 through 3 years of age, “manufacturers of beverages that are not juices, such as milk or water, use a RACC of 120 mL for this age group (4 fl oz)” (Section III.B.9). As stated in our enclosed comments submitted to the docket in January 2019 regarding FDA’s draft guidance on this topic, milk and/or soy-based drinks intended for toddlers/older infants are formulated for children 1-3 years of age with specific nutritional needs and may not fit under current RACC criteria for certain beverages.

Growing up milks (GUM) are used following a young child’s transition to solid foods and can play a role in complementing the diet of this population to support continued growth and development. Oral nutrition supplements (ONS), a different category of products, are formulated to complement or modify nutrient intake and are often used following a recommendation from a healthcare provider.

We understand RACCs are determined based on consumption data; however, most databases – such as the National Health and Nutrition Examination Survey (NHANES) – do not include sufficient data on milk and/or soy-based toddler drinks for this purpose. Therefore, milk consumption data may be the most comparable reference for these products. Data from the Feeding Infants and Toddlers Study (FITS 2016)³ show that young children ages 12 to 24 months have a mean intake of 5.5 fl oz of milk per eating occasion, and for children ages 24-36 months the mean intake per eating occasion is 5.7 fl oz. Based on

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.

³ Nestlé Feeding Infants and Toddlers Study (FITS 2016) unpublished data.

this data, 4 fl oz may not adequately represent the most appropriate RACC for milk/milk-based products for this age group.

We therefore recommend FDA:

- 1) Effectuate a stay of action for – or otherwise remove – a portion of Section III.B.9 of the final guidance document. More specifically, we request and recommend the second sentence in this section be amended as follows, to account for a greater than 120 mL RACC for certain “beverages,” while retaining a recommended 120 mL for other non-juice beverages:

“However, we recommend that manufacturers of *certain* beverages that are not juices, such as water or flavored water, use a RACC of 120 mL for this age group (4 fl oz). We also note that milk-based beverages as well as specially formulated milk and/or soy-based drinks intended for young children may be subject to a RACC greater than 120 mL (4 fl oz).”

Such an administrative stay of action or revision to the guidance could thusly account for data that supports greater intake of some beverages, like milk and specially formulated milk and/or soy-based drinks intended for this age group.

- 2) Due to the varying portion sizes and formulation of these products, we request FDA not to establish or enforce a RACC for these products at this time.

We recognize these comments apply to a non-binding guidance document, but we are nevertheless apprehensive about how FDA personnel may reference or otherwise rely on this guidance document when reviewing product labeling.⁴ Amending the guidance document would provide all stakeholders with not only an appropriate caveat for RACCs, but also provide clarity and consistency within the context of regulatory compliance and review.

We appreciate that the final guidance did “acknowledge that more products for infants and children 1 through 3 years of age are currently on the market than were available in 1993 (81 FR 34000 at 34031-34032),” and that FDA has “yet to establish RACCs for many such products,” but intends to “review available information... and consider next steps.” However, in the meantime, we remain concerned that FDA investigative, compliance, and review staff will use the current version of the final guidance document to enforce such RACCs for those very products for which FDA has not established an appropriate RACC. Further revisions to Section III.B.9 of the guidance, in the manner described above, will help clarify such point.

Thank you for the opportunity to provide these additional comments. Please let us know if you have any questions.

Sincerely,



Mardi K. Mountford, MPH
President
Infant Nutrition Council of America



Robert Rankin
Executive Director
Healthcare Nutrition Council

Enclosed: FINAL INCA-HNC Comments to FDA Food Labeling Serving Sizes 1.4.19

⁴ Indeed, in order to address federal agency reliance on guidance documents at a broader level, two recent Executive Orders were recently announced: [“Executive Order on Promoting the Rule of Law Through Improved Agency Guidance Documents”](#) and [“Executive Order on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication.”](#)



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 companies¹ 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 manufacturers² 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