



October 11, 2018

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket Number FDA-2018-N-2381-0317 titled “The Food and Drug Administration’s Comprehensive, Multi-Year Nutrition Innovation Strategy, Extension of the Comment Period”

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) and the Infant Nutrition Council of America (INCA) are jointly responding to the notice published August 16, 2018 in the *Federal Register* by the U.S. Food and Drug Administration (FDA) entitled “FDA’s Comprehensive, Multi-Year Nutrition Innovation Strategy.” HNC is an association representing manufacturers¹ 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 is an association of manufacturers of infant formula and growing up milks whose member companies² 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.

Following are HNC and INCA’s joint comments on FDA’s Nutrition Innovation Strategy (NIS).

Modernizing Healthy Definition and Claims

A key element of the NIS is modernizing claims, including addressing the use of the term “healthy” on labeling and finalizing the definition that reflects current nutrition science and supports public health. HNC and INCA strongly support adopting a modernized definition prior to making a decision on its suitability and use with a “healthy” icon. While considering a revised “healthy” definition, HNC and INCA encourage FDA to engage HNC, INCA, and other stakeholders such as health care providers, in order to fully understand the implications of how the definition could encompass foods for special dietary use (FSDU). FSDUs include oral nutrition supplements for toddlers, children, and adults with special dietary needs. The populations who rely on ONS in the FSDU category often have differentiated health needs and goals compared to the general population. For example, for young children with autism and food aversions, these products complement their diet and are especially important for their growth, development, and overall health.

Additionally, malnutrition can be a significant problem for older adults. The World Health Organization’s (WHO) Guidelines Integrated Care for Older People (ICOPE) recommends oral supplemental nutrition with dietary advice for older people affected by undernutrition (Recommendation 2).³ The ICOPE notes that it is important to consider specially formulated supplementary foods to help meet the nutritional requirements of older people as protein absorption decreases with age. We encourage FDA to consider WHO’s ICOPE Recommendation 2 as part of the overall Nutrition Innovation Strategy.

¹ HNC members are Abbott Nutrition, B. Braun Medical Inc., Nestle Healthcare Nutrition, and Nutricia North America.

² INCA members are Abbott Nutrition, Gerber Products Company, Perrigo Nutritionals, and Reckitt Benckiser.

³ “WHO Guidelines on Integrated Care for Older People”, World Health Organization, 2017.

<<http://www.who.int/ageing/publications/guidelines-icope/en/>>

Although FSDUs are designed for consumers within a subset of the general population, who have differentiated nutrition and health needs, these products are required to comply with general food labeling rules, such as the Nutrition Labeling and Education Act (NLEA). Attached to this submission are the previously submitted HNC and INCA comments on considerations for the definition of “healthy” as it specifically pertains to FSDU. HNC and INCA recommended the following:

1. The definition of “healthy” should include nutrients or foods which make positive contributions to the diet, as well as nutrients or foods which should be limited. FDA initially requested information on whether the claim be defined based on nutrient criteria or if it should be changed to food group criteria. HNC and INCA are concerned that limiting the definition to food group criteria would prohibit the claim entirely on formulated foods. Therefore, we recommend the definition of “healthy” be based on updated nutrient criteria *or* food group criteria. This would allow the “healthy” claim to be used under either criteria, as appropriate. We believe this approach provides the flexibility necessary to promote public health across different groups of consumers, and is also realistic with consumer’s needs and preferences.
2. HNC and INCA have proposed (in previous comments attached to this submission) special considerations for highly nutrient dense foods such as ONS which serve populations with differentiated health goals versus the general population. For example, in ONS products for populations at risk of or with malnutrition, the primary health goal is to increase nutritional intake for weight gain and/or weight maintenance. Formulas may also be used as sole source or complementary nutrition for infants and children who have special needs for growth and development.
3. HNC and INCA also proposed that the use of the term “healthy” be defined for foods specifically marketed to infants and young children under the age of 3 to align with the nutritional labeling age groups in FDA’s final rule on Nutrition Facts labeling.

Expanded Nutrient Content Claims

HNC and INCA support FDA providing guidance on the use of nutrient content claims for food marketed to infants and young children, specifically those under 2 years of age. FDA’s current regulatory limits on nutrient content claims for infant and toddler food does not adequately allow for the public dissemination of valuable scientific information regarding the role of early food and nutrient intake on the health and development of healthy eating habits. Claims on food marketed for children under 2 years of age are limited to statements about vitamins and minerals in the context of the Daily Value and claims related to food taste, such as unsweetened or unsalted (21 CFR 101.13(q)(3)(i)). FDA regulations prohibit nutrient content claims on food for children under the age of 2, resulting in parents and caregivers having a dearth of information about the nutrient content of these foods, which obstructs their ability to make sound dietary choices for this population.

During the rulemaking process for revising the Nutrition Facts format and Daily Values, FDA acknowledged the change in the scientific landscape and formalized Daily Values for total fat, saturated fat, cholesterol, sodium, and added sugars for children 1 through 3 years. For infant food, FDA also made mandatory the declaration of saturated fat, cholesterol, and added sugars, and defined Daily Values for carbohydrates and total fat. We understand and agree with FDA’s goal of updating the Nutrition Facts label to help consumers comprehend the information and maintain healthful dietary practices.⁴ Therefore, we recommend FDA provide guidance on “source of” claims for protein, fiber, vitamins, and minerals; and “relative” claims for sodium, saturated fat, and total and added sugars. Consumers and the scientific

⁴ Federal Register. Vol. 79, No. 41, Monday, March 3, 2014. Page 11891. Food Labeling: Revision of the Nutrition and Supplement Facts Labels: Proposed Rule.

community would support FDA guidance on these claims as they are supported by science, dietary intake data,^{5,6,7} and consumer interest when making healthy dietary choices for young children.

Modernizing Ingredient Labels

HNC and INCA support FDA's intent to modernize ingredient labeling through the NIS. For example, we recommend this new regulatory framework to include a suitable set of options provided by FDA for manufacturers to choose, two of which could include:

- 1) Simplified ingredient naming as proposed by the DSM petition;⁸ or
- 2) Maintaining current naming, such as using the chemical name, to enable manufacturers to provide greater detail through labeling when desired, and to differentiate nutrient forms to support innovation.

Fostering Innovation

HNC and INCA encourage FDA to clarify regulatory requirements and definitions surrounding the FSDUs and medical food categories. The unclear regulatory environment creates additional obstacles for manufacturers developing FSDUs and medical foods. Additionally, as FDA's interpretation of the medical foods category is quite narrow, it creates an unclear scenario for manufacturers to develop new, innovative products that truly could be effective tools in the nutritional management of numerous diseases and health related conditions.

We fully support FDA in seeking ways to simplify labeling information for the benefit of consumers. We look forward to further dialogue on specific changes that may benefit consumers who rely on specialty food products which are formulated to help meet their distinct health needs and goals.

Thank you for the opportunity to provide comments on FDA's Nutrition Innovation Strategy. Please contact us with any questions you may have.

Sincerely,



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⁵ Bailey, Regan L.; Catellier, Diane J.; Jun, Shinyoung; Dwyer, Johanna T.; Jacquier, Emma F.; Anater, Andrea S.; Eldridge, Alison L. Total Usual Nutrient Intakes of U.S. Children (Under 48 Months): Findings from the Feeding Infants and Toddlers Study (FITS) 2016. *The Journal of Nutrition*. <https://doi.org/10.1093/jn/nxy042>.

⁶ Anater, Andrea S.; Catellier, Diane J.; Levine, Burton A.; Krotki, Karol P.; Jacquier, Emma F.; Eldridge, Alison L.; Bronstein, Katherine E.; Harnack, Lisa J.; Lorenzana Peasley, Julia M.; Lutes, Anne C. The Feeding Infants and Toddlers Study (FITS) 2016: Study Design and Methods. *The Journal of Nutrition*. <https://doi.org/10.1093/jn/nxy035>.

⁷ Reidy et al. *BMC Nutrition* (2017) 3:5 DOI 10.1186/s40795-016-0124-0.

<https://bmcnutr.biomedcentral.com/articles/10.1186/s40795-016-0124-0>

⁸ Citizen petition from DSM Nutritional Products LLC: <https://www.regulations.gov/document?D=FDA-2017-P-6211-0001>.