INFANT NUTRITION COUNCIL OF AMERICA

Healthcare Nutrition Council
529 14th Street, NW • Suite 750 • Washington, DC 20045

April 26, 2017

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

RE: Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments (FDA-2016-D-2335)

Dear Division of Dockets Management,

The Infant Nutrition Council of America (INCA) and the Healthcare Nutrition Council (HNC) are jointly commenting on the US Food and Drug Administration's (FDA) request for information and comments on the "Use of the Term 'Healthy' in the Labeling of Human Food Products" (FDA-2016-D-2335), which was published in the *Federal Register* on September 28, 2016. INCA is an association of manufacturers and marketers of formulated nutrition products, e.g., infant formulas and adult nutritionals, whose member companies produce over 95% of the infant formula consumed in the US.* HNC is an association representing manufacturers of enteral nutrition formulas, parenteral nutritional formulas, supplies and equipment.†

INCA and HNC support the FDA's efforts to update the definition of "healthy" to reflect the latest scientific evidence and better assist consumers in making healthy dietary choices. We are also supportive of the Agency's adaptations in requirements on the basis of different food types in 21 CFR Part 101.65(d)(2)(i) (e.g., raw fruits and vegetables in category (A) compared to formulated foods in categories (E) or (F)).

Before addressing our general and specific comments on the use of the term "healthy," we would like to clarify a few of the terms that will be used throughout these comments. The term "processed food" is intended to mean those foods that have been subjected to a deliberate change (such as heating, cooling, mixing, dehydration, etc.) and/or to which other ingredients, nutrients or additives have been added prior to being packaged for sale to the consumer. When referring to "fortified foods," we refer to FDA's Fortification Policy found at 21 CFR Part 104.20 (Subpart B). As such, a fortified food would be a food to which some or all of the nutrients listed at 21 CFR Part 104.20(d)(3) have been added in accordance with the constraints noted within the policy. The term "formulated foods" is used to refer to a particular class of both processed and fortified foods that are specifically composed of certain nutrients or physical characteristics intended to support a life phase, manage a dietary need that results from a physical, physiological, pathological or other condition, and/or address a nutritional deficiency. Formulated foods include infant formulas, toddler formulas and growing up milks (GUMs), as well as foods that meet FDA's definition of Foods for Special Dietary Use (FSDU), per 21 CFR Part 105, including oral nutritional supplements (ONS) and other foods for special dietary use.

INCA and HNC agree that it is important to allow the use of the term "healthy" in the context of nutrient content claims for a broad range of foods. Processed and fortified foods offer practicality and convenience to consumers, and are an important component of American diets. Therefore, it is critical that manufacturers are able to differentiate these foods on the basis of nutrient content, which helps incentivize industry to continually reformulate and innovate their products to improve healthful attributes and assist consumers in selecting more healthful choices. Further, nutrient content claims are allowed for all foods that qualify for a claim under the Nutrition Labeling and Education Act (NLEA) regardless of whether nutrients are intrinsic or fortified, as well as how the food is processed.

*INCA members are Abbott Nutrition, Mead Johnson Nutrition, Gerber Products Company and Perrigo Nutritionals.
† HNC members are Abbott Nutrition, B. Braun Medical Inc., Nestle Healthcare Nutrition and Nutricia North America.

Further, with regard to the Agency's final rule on nutrition labeling, INCA and HNC support that the new format for nutrition facts labels provide greater transparency to consumers. We therefore believe companies should be using the new format in order to make a "healthy" claim under any new definition that results from this rulemaking.

INCA and HNC also request that FDA consider the following suggestions in the revision of the definition for "healthy."

A. <u>We recommend permitting the term "healthy" to be used in the labeling of foods intended for children age 1 through 3 years</u>

In addition to those foods for which nutrient content criteria are currently defined in 21 CFR Part 101.65(d)(2)(i) for use of the term "healthy" (e.g., raw fruits and vegetables, single-ingredient or mixture of frozen or canned fruits and vegetables, enriched cereal grain products, raw single-ingredient seafood or game meat, meal products or main dish products, or other foods not encompassed by the previous), INCA and HNC recommend that the FDA define the requirements for the use of the term "healthy" for foods specifically marketed for children 1 to 3 years of age.

To promote consistency with the new Dietary Reference Values (DRVs) and Recommended Dietary Intakes (RDIs) recently finalized by FDA, which include values for children 1 to 3 years of age, INCA and HNC believe the use of the term "healthy" should be permitted for use on foods specifically purported for young children ages 1 year and older. This will offer parents another tool to assist in making healthy food choices for their young children.

INCA and HNC recommend the following nutrient content criteria for processed/fortified/formulated foods labeled as "healthy" for young children 1 to 3 years of age. It should be noted for those foods in which there is no established reference amount customarily consumed (RACC), levels should be recognized per labeled serving.

If the food is…	**The fat level must be…**	**The sodium level must be…**	**The food must contain…**
Specifically purported for children 1-3 years of age	Made up of a majority of mono- and polyunsaturated fats or the product has 2 gram or less saturated fat per RACC and less than 0.5 gram trans fat per RACC	300 milligrams or less per RACC	At least 10% of the RDI or DRV per RACC of at least one of the following: protein, vitamin D, calcium, dietary fiber, potassium, vitamin E, iron or the product is predominantly whole grains with a minimum amount of whole grain per RACC of 2 grams or the product provides an amount of fruit and/or vegetable equivalent to ¼ cup per RACC

Below are additional comments supporting the above criteria for use of the term "healthy" for products specifically purported for young children.

1. *Fat*
   Consistent with the 2015-2020 Dietary Guidelines for Americans (DGAs), which emphasize type and quality of fat, the fat content criteria for the use of the term "healthy" should reflect what has been defined in the FDA's recent guidance to industry (e.g., "Guidance for Industry:

Use of the Term 'Healthy' in the Labeling of Human Food Products"). Therefore, products labeled as healthy purported for young children 1 to 3 years of age should either have the majority of fat as mono- and polyunsaturated fats or the food should contain 2 grams of saturated fat or less per RACC, which is 20% of the DRV for this population.

2. *Saturated Fat*
In recent iterations of the DGAs, it has been recommended that saturated and trans fats be limited and replaced with a higher proportion of mono- and polyunsaturated fats. In the 2015-2020 DGAs, it is recommended that less than 10% of daily calories come from saturated fat. However, the current criteria for using the term "healthy" requires that a product meet the nutrient content claim of "low saturated fat" as defined in 21 CFR Part 110.62(c)(2) (e.g., 1 gram or less of saturated fatty acids per RACC and not more than 15% of calories from saturated fatty acids).

However, the FDA acknowledges that saturated fats are essential in fostering growth and maintaining good health during critical stages of development, which includes young children 1 to 3 years of age.[1] However, the FDA also considered that cardiovascular disease can begin in childhood and that the evidence supports limiting saturated fat intake to less than 10% of calories in establishing a DV for saturated fat for children 1 to 3 years of age. INCA and HNC believe the current limit on saturated fat in the healthy definition could disqualify from making the claim some foods which would be considered healthy for this population (e.g., avocados, low-fat milk); therefore, the FDA should consider a higher limit on saturated fats for this age group. We propose FDA consider 2 grams of saturated fat per RACC as an acceptable limit on saturated fat.

Food	**Serving size**	**Saturated Fat**
Low fat 1% milk	8 fl oz	1.5 g
Low Fat 1% milk	6 fl oz	1.1 g
Milk 2% Fat	8 fl oz	3 g
Milk 2%	6 fl oz	2.25 g
Avocado	¼ cup pureed	1.22
Low fat Vanilla Yogurt	6 oz	1.37 g
Peanut butter	1 tbsp	1.65 g
Ground beef, 7% fat	1.5 oz	1.4 g

Source: US Department of Agriculture (USDA) Standard Reference

3. *Cholesterol*
Evidence on cholesterol has evolved and now indicates that there is no appreciable relationship between dietary cholesterol and serum cholesterol, leading the 2015-2020 DGAs to exclude the previous recommendation to limit dietary cholesterol to less than 300 mg per day. Therefore, we believe the criteria for use of the term "healthy" should reflect this update by eliminating the requirement for a cholesterol limit, including for foods purported for young children.

4. *Sodium*
The new DV for sodium is 1,500 milligrams per day for children 1 to 3 years of age. Therefore, we suggest the sodium criteria for use of the term "healthy" be established to reflect 20% of this DV (e.g., 300 milligrams) per RACC or for foods which are 50 grams or less, a RACC of 30 grams or less. In lieu of these criteria, products meeting the Agency's voluntary sodium guidance levels, once finalized, should also be considered to have a "healthy" level of sodium.

5. *Added Sugar*
As part of the final NFL rule, the FDA established, for the first time, a DV for added sugars, including a level of 25 grams/day for children ages 1 to 3 years of age.

For certain formulated foods such as toddler formulas, nearly all of the sugar content is considered added sugar under FDA's new definition. In these products, sugar sources are an easily digestible source of carbohydrate and play an equally critical role in masking negative sensory attributes of highly nutrient dense foods (e.g., mineral taste). INCA and HNC members carefully manufacture toddler formulas to maintain an acceptable palatability for young children's preferences without compromising nutrient density. INCA and HNC believe that manufacturers of these products and other foods for this population should disclose the amount of added sugars on the label per the final rule on nutrition labeling and the new format.

6. *Beneficial Nutrients*
In the final NFL rule, it was recognized that vitamins A and C are no longer nutrients of public health concern and thus no longer required on product labels; however, vitamin D and potassium are nutrients of public health concern and will now be required on product labels. The 2015-2020 DGAs also recognized calcium and dietary fiber as nutrients of public health concern. Iron has also been recognized by the Agency as a nutrient of public health concern for children 1 to 3 years of age. INCA and HNC support the codification of these nutrients in the criteria as they are only in guidance for industry and not in final regulation. Further, specifically for young children, vitamin E is also a nutrient of public health concern and it would be beneficial to include within the criteria for use of "healthy" in products specifically purported for young children 1 to 3 years of age as recent data has shown it is inadequately consumed by a significant portion of this population.[3,4] Finally, because adequate protein intake in this age group is important for normal growth and development, we recommend that protein be maintained in the list of "beneficial nutrients."

   In conclusion, INCA and HNC recommend that the "beneficial nutrient" criteria for use of the term "healthy" in food labeling be specified as at least 10% of the RDI or DRV per RACC for at least one of the following beneficial nutrients: protein, vitamin D, calcium, dietary fiber, potassium, vitamin E or iron.

7. *Food Groups to Encourage as an Alternative Criteria*
As an alternative to delivering a specific nutrient, healthy foods should promote the intake of food groups that are encouraged in a healthy diet. Specifically, a product comprised of a significant amount of fruit and/or vegetable or whole grain should be able to make a healthy nutrient content claim,

   To qualify as meeting the whole grain requirement for a healthy claim for this age group, whole grains should comprise 50% of the grain portion and the food should contain no less than 2 grams of whole grain per RACC for foods with a RACC less than 15 grams and 4 grams or more whole grain for foods with a RACC of 15 grams or more.

   To qualify as meeting the fruit and/or vegetable requirement for a healthy claim for this age group, the amount of fruit and/or vegetable should an amount equivalent to ¼ cup fruit and/or vegetable (approximately 10% of the recommended intake of 2 cups/day) per RACC.

B. <u>We recommend FDA establish specific criteria for the use of "healthy" for oral nutritional supplements (ONS), a type of food for special dietary use, for ages 4 years and older</u>

Currently, the term special dietary use is defined in 21 CFR Part 105.3(a)(1) and (2) as the following:

> *(1) The term special dietary uses, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:*
>
> *(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not*

limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.

INCA and HNC members manufacture high quality, scientifically-based and nutrient-dense foods for special dietary use which are intended to provide supplemental or sole source nutrition for individuals who are at risk of malnutrition or cannot achieve baseline nutritional intake from a normal diet. These products are often referred to as oral nutritional supplements (ONS) and often provide a complete and balanced profile of macro- and micronutrients. The populations who consume ONS often have nutritional goals which are vastly different from the general, healthy population. Therefore, we suggest that FDA uniquely define terms for "healthy" for ONS:

If the food is…	The fat level must be…	The saturated fat level must be…	The sodium level must be…	The food must contain…
Food for special dietary uses	Made up of a majority of mono- and polyunsaturated fats which are declared on the label	Not more than 15% of calories from saturated fatty acids	460 milligrams or less per RACC and per labeled serving	At least 10% of the RDI or DRV per RACC of protein and at least two of the following nutrients: vitamin A, vitamin C, vitamin D, vitamin E, choline, calcium, magnesium, dietary fiber, iron, potassium

Below are additional comments supporting the above nutrient criteria for use of the term "healthy" for foods for special dietary uses.

1. *Fat*
   As noted above, consistent with the 2015-2020 DGAs, which emphasize type and quality of fat, the fat content criteria for the use of the term "healthy" should reflect what has been defined in the FDA's recent guidance to industry (e.g., "Guidance for Industry: Use of the Term 'Healthy' in the Labeling of Human Food Products"). Therefore, the use of the term "healthy" should emphasize the majority of fats as mono- and polyunsaturated fats as opposed to a total fat limit for foods for special dietary uses.

2. *Saturated Fat*
   As noted above, in recent iterations of the DGAs, it has been recommended that saturated and trans fats be limited and replaced with a higher proportion of mono- and polyunsaturated fats. In the 2015-2020 DGAs, it is recommended that less than 10% of daily calories come from saturated fat. However, the current criteria for using the term "healthy" requires that a product meet the nutrient content claim of "low saturated fat" as defined in 21 CFR Part

110.62(c)(2) (e.g., 1 gram or less of saturated fatty acids per RACC and not more than 15% of calories from saturated fatty acids).

The new requirement proposed by FDA in their guidance that the majority of fats be provided as mono- and polyunsaturated fatty acids will help ensure the recommendations in the dietary guidelines are met as it mandates a replacement of saturated and trans fats with mono- and polyunsaturated fats. As it pertains to foods for special dietary use in particular, the framework of the current limit for saturated fat of less than 1 gram per RACC currently precludes some ONS from using the term "healthy" despite the fact that they provide a majority of fats as mono- and polyunsaturated fatty acids and provide less than the other requirement of 15% of calories as saturated fatty acids.

This may be due to presence of specific lipids, with a targeted fatty acid profile, selected for a demonstrated benefit in these populations. Thus, the existing quantitative limit in addition to a percentage of calories limit of the food itself results in overly restrictive and often conflicting requirements which specifically penalize nutrient-dense foods. Therefore, we recommend removing the quantitative limit of 1 gram or less per RACC and maintain a limit for saturated fat as less than 15% of total calories for foods for special dietary uses.

3. *Cholesterol*
   As noted above, evidence on cholesterol has evolved to indicate that there is no appreciable relationship between dietary cholesterol and serum cholesterol, leading the 2015-2020 DGAs to exclude the previous recommendation to limit dietary cholesterol to less than 300 milligrams per day. Therefore, we believe that the criteria for use of the term "healthy" should reflect this update by eliminating the requirement for a cholesterol limit.

4. *Sodium*
   The updated DV for sodium is less than 2,300 milligrams per day for individuals 4 years and older. Therefore, we suggest that the sodium criteria for use of the term "healthy" be established to reflect 20% of this DV (e.g., 460 milligrams).

5. *Added Sugar*
   As part of the final NFL rule, the FDA established, for the first time, a DV for added sugars, including a specific level (50 grams/day) for adults and children ages 4 years and older. INCA and HNC members manufacture nutrient-dense foods for special dietary use for individuals who cannot meet the baseline nutrient intakes through normal diet and/or are at risk of, or have, malnutrition. The populations who most benefit from these foods often need to maintain or increase weight, and thus, have different nutrient intake goals from the general population.

   For formulated foods such as ONS, nearly all of the sugar content is considered added sugar under FDA's new definition. In these products, sugar sources are an easily digestible source of carbohydrate and play an equally critical role of masking negative sensory attributes of highly nutrient dense foods (e.g., mineral taste). INCA and HNC members carefully manufacture foods for special dietary use to maintain an acceptable palatability for compliance of intake without compromising nutrient density. Because the intended populations have primary health goals different from the general healthy population, the role of these specialized foods can help improve nutritional status and health outcomes, and because nutrient density can compromise palatability and acceptability of the product, we recommend FDA exclude an added sugar limit for ONS.

6. *Beneficial Nutrients*
   Foods for special dietary use provide supplemental or sole source nutrition to individuals who have a special dietary need, which can exist due to age, disease or health condition, pregnancy or lactation, etc. Such foods, including ONS, are fortified to provide macronutrients, micronutrients, and other dietary properties to help supplement the diet in accordance with a special dietary need.

For many individuals, various physical, social, emotional and socioeconomic issues impact their ability to consume adequate food and nutrition, which places them at high risk for nutritional deficiencies and challenges, including malnutrition. ONS products can provide a nutrient-dense solution to increase or maintain nutritional intake and mitigate nutritional deficiencies or adverse health outcomes. As ONS products provide a significant source of the diet, we believe it is reasonable to expand the criteria for beneficial nutrients to include not only the nutrients of public health concern, but also the "shortfall nutrients" noted in the 2015-2020 DGAs. These nutrients include vitamins A, C, D, E, choline, calcium, magnesium, dietary fiber, potassium as well as iron.

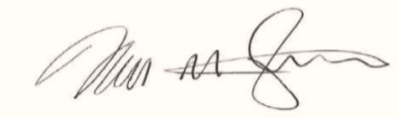
In addition, because the intended populations for ONS often have suboptimal nutrient intake, we recommend that protein be maintained in the list of "beneficial nutrients." Protein is critical in maintaining the diet quality of these populations and in preventing involuntary weight loss and protein-energy malnutrition.

In conclusion, INCA and HNC recommend increasing the requirements for beneficial nutrients beyond the criteria defined for general foods, so that it is required to provide a minimum of at least 10% of the RDI or DRV per RACC for protein in addition to at least two of the shortfall nutrients (e.g., vitamin A, vitamin C, vitamin D, vitamin E, choline, calcium, magnesium, dietary fiber, iron, potassium). However, we do note instances in which FSDUs may be formulated for a population or particular dietary need whereby protein requirements would not provide a specific nutritional or physiological benefit. In such instances in which the intended population would not benefit from the criteria for protein as noted above, the product would need to provide the necessary level of shortfall nutrients as noted above. These criteria are suitable to include a variety of ONS products, including those that are intended for supplemental nutrition to address a special dietary need.

In summary, we applaud FDA's efforts to improve public health by revising the definition of "healthy" to more closely align with the latest scientific evidence, existing nutrition labeling regulations and consumer eating habits. To help enhance these efforts, we request that the above requests be taken into consideration as this definition is finalized.

We appreciate the opportunity to provide comments on this impactful regulation. Please let us know if there are any questions.

Sincerely,



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References

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