
Healthcare Nutrition Council

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

Definition of Distinctive Nutritional Requirement

“Distinctive nutritional requirement” refers to the clinical need for a specific nutritional intake (compared to the intake of healthy populations) which may exist by reason of abnormal physiological manifestation or physical impairment* associated with a disease or condition, the dietary management of which results in clinically meaningful improvements, including but not limited to nutritional status, health outcomes, or quality of life.

****“Abnormal physiological manifestation or physical impairment” includes the following conditions associated with acute and chronic diseases or health conditions:***

***(i) a limited, impaired or disturbed capacity to ingest, digest, absorb, metabolize or excrete ordinary food or certain nutrients or metabolites, or
(ii) other medically-determined requirements for nutrients/other food substances of biological value.***

Four Key Pillars to ensure a patient-centric approach to the Medical Foods category:

- 1) Focus on patients’ complete nutritional requirements, beyond just nutrient levels:** Our proposed definition of “distinctive nutritional requirement”, as indicated above, appropriately narrows the category of Medical Foods to products formulated with a high standard of scientific rigor and quality, while also providing sufficient flexibility to address overall patient needs, and supporting innovations in nutrition science. While necessary adjustments to the intake of essential nutrients is an example of a distinctive nutritional requirement, it should not be the **only** accepted criteria for the classification of a product as a Medical Food. This restrictive interpretation creates a scenario where other products, like standard enteral tube feedings, are excluded from the same regulatory category despite their critical role in the dietary management of the disease or medical condition and their benefit to patients (see below for proposed types of distinctive nutritional requirements).
- 2) This definition of “Distinctive nutritional requirement” is intended to be taken in a context in which it is impossible, impractical, unsafe or nutritionally or clinically disadvantageous for patients to meet their nutritional needs through the exclusive consumption of foods other than Medical Foods.**
- 3) Keep positive health outcomes for patients as the core goal:** The definition should inform the development of Medical Foods that are specifically formulated to meet the “distinctive nutritional requirements” of patients in order to maintain/improve nutritional status and overall health status, clinical outcomes and quality of life. The definition should also inform the development of Medical Foods when it is impossible, impractical or unsafe for these patients to meet their “distinctive nutritional requirements” exclusively through the normal diet and/or the patients would have a nutritional or clinical disadvantage from consuming the normal diet alone rather than Medical Foods. In other words, the definition

should not be limited to **only** those Medical Foods **necessary** to keep patients alive. The development of Medical Foods which support positive health outcomes for patients is more consistent with population-based public health goals and nutrition guidelines.

- 4) **Recognize the continuum of disease severity can amplify the need for Medical Foods:** The severity of a disease/condition can vary along a spectrum, and the most severe patient may be living with additional comorbidities which necessitate more complex nutritional modifications; may have or be at risk for malnutrition; and may require tube feeding. While all patients with a disease/condition which necessitates nutritional modifications may benefit from incorporation of a Medical Food into their medical nutrition therapy care plan, it's important that the definition not be used to restrict availability of disease-specific Medical Foods on the basis of the "healthiest" patient on the spectrum of severity. The patients on the severe end of the spectrum should not be precluded from having access to Medical Foods tailored to their needs because some patients living with the same disease or condition, with a lesser severity, can successfully modify their normal diet with regular foods alone.

Proposals for the implementation of above definition of distinctive nutritional requirement:

"Specific nutritional intake"

- 1) The term used in the Medical Food statutory definition is "distinctive **nutritional** requirement", not "distinctive **nutrient** requirement", indicating the intent is broader than just an adjustment up or down, or a narrower range of tolerance of essential nutrients; while these are certainly examples, they should not be exhaustive. Distinctive nutritional requirement should incorporate a broader spectrum of types of nutritional and dietary modifications, encompassing the use of both nutrients and other food substances of biological value, which are a critical part of the dietary management of the disease or medical conditions. Examples could include products intended to address (non-exhaustive):
 - a) Adjustments in the delivery of the food to enable nutritional intake (*e.g.*, enteral tube feeding);
 - b) Adjustments in nutritional intake including nutrients that do and do not have a dietary reference intake (DRI) (*e.g.*, essential and conditionally essential macro/micronutrients, amino acids, fatty acids and / or other food substances of biological value);
 - c) Adjustments, comparative to the healthy population, in the way one monitors and continually adapts their nutritional intake (*e.g.*, diabetes).
 - d) Adjustments of the cellular energy metabolism (*e.g.*, ketogenic products)
- 2) The definition should be forward-thinking to encompass the potentially altered distinctive nutritional requirement of an increasingly older population who frequently have multiple chronic and acute conditions. Nutrition, including Medical Foods, can have an important role in driving down overall healthcare costs by keeping older adults healthy, functional, and in their homes.

Types of Medical Foods under this distinctive nutritional requirement framework

- 1) The definition should permit 1) nutritionally complete formulas; 2) nutritionally incomplete formulas, including individual “modular” type products that may be mixed with other products before use (*e.g.*, modular of protein, carbohydrate, fat, fiber, vitamin and mineral and substances which belong to or are components of one of those categories); 3) formulas for metabolic (genetic) disorders in patients over 12 months of age; and 4) oral rehydration products.

- 2) The definition should ensure that tube feeds (specially formulated and processed products) are Medical Foods. These products are classic examples of modifications necessary to sustain life for patients who have a physical impairment which precludes them from consuming foods orally. They are often relied upon as the sole source of nutrition and are used under medical supervision.

Questions for Discussion

- 1) We would like to further understand FDA's thinking on the distinction between dietary management of a disease and mitigating a disease. Is restoring and/or supplementing a biological pathway (rather than changing the biological pathway) an appropriate frame of reference to understand the classification of food versus drug mechanism in disease management?
- 2) In the definition noted above, is "clinically meaningful improvements" an appropriate term to use?
- 3) Above, HNC provided our explanation of the term "abnormal physiological manifestation or physical impairment". Does FDA have any additional thoughts on HNC's rationale or would FDA interpret "abnormal physiological manifestation or physical impairment" differently?