



Certification Board for Nutrition SpecialistsSM

October 15, 2013

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

Re: Draft Guidance for Industry: Frequently Asked Questions About Medical Foods; Second Edition. **78 Fed Reg 49271-49272 (Aug 13, 2013). Docket ID:** FDA-2013-D-0880

Dear Sir or Madam:

I am writing on behalf of the Certification Board for Nutrition SpecialistsSM (CBNS). The CBNS is the foremost credentialing body for advanced degreed clinical nutritionists. Our Certified Nutrition Specialist[®] (CNS) certificants include many MDs, DOs and nutrition professionals holding Masters or Doctorates in nutrition or a related health field. All of our certificants are likely to be affected by this guidance. As a scientific board at the highest level of nutrition research and evidence based nutrition care, we respectfully request your consideration of the following comments to this draft guidance.

The CBNS has the following concerns:

1. Regarding Section II, Questions and Answers:
 - a. The criteria outlined in #2 are misapplied to exclude chronic disease. Understanding of the science of epigenetics has uncovered a broad range of diseases with genetic influence. Genetically influenced diseases are not restricted to those due to inborn errors of metabolism, and in fact include many chronic diseases which are named as exclusions to these guidelines, such as type 2 diabetes.
 - b. Furthermore, medical foods for many of the excluded diseases and conditions meet the criteria in the FDA regulations at **21 CFR 101.9(j)(8)**. For example, medical foods for type 2 diabetes specifically excluded in #23 meet the criteria as follows:

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1. *“It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube.”*

Comment: Certain medical foods are specially formulated and processed to meet the specific nutritional requirements of those with type 2 diabetes (they may include these components-low carbohydrate, healthy fat, fiber, and nutrients that have been demonstrated to lower blood sugar and insulin levels, such as cinnamon). (1)

2. *“It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone”;*

Comment: Type 2 diabetics have specific medical needs to correct impairments in cellular uptake of glucose and an impaired capacity to metabolize carbohydrates. (2)

3. *“It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;”*

Comment: Certain nutrients have been proven effective in the management of the unique nutrient needs resulting from type 2 diabetes. For example, omega 3 fats have been shown to enhance insulin sensitivity. (3)

4. *“It is intended to be used under medical supervision”;* and

Comment: Type 2 diabetics have need for ongoing evaluation and education by physicians and qualified nutrition professionals.

5. *“It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.”*



Comment: The management of type 2 diabetes requires recurring medical care and nutritional instruction.

2. Having these foods labeled properly allows the practitioner to choose the appropriate intervention and educate the patient on the appropriate use of the medical food.
3. Restricting medical foods in the way envisioned in the Draft Guidance will unnecessarily confuse patients who are struggling to regain health. Restricting patient access to appropriately identified medical foods would be a barrier to improvement of our nation's health and runs counter to the national policy direction of team-based, patient-participatory healthcare.

For these reasons, CBNS respectfully requests that the FDA allow the labeling of medical foods to continue to be broadly applied and to encompass those medical foods tailored to the excluded conditions and disease states.

Sincerely,

Sidney J. Stohs, PhD, FACN, CNS, ATS
President, Certification Board for Nutrition Specialists

- (1) Khan, A et al. "Cinnamon Improves Glucose and Lipids of People With Type 2 Diabetes". *Diabetes Care*, 2003 Dec, 26 (12): 3215-3218.
- (2) Bonadonna, Ricardo. "Alterations of Glucose Metabolism in Type 2 Diabetes Mellitus. An Overview." *Reviews in Endocrine and Metabolic Disorders* 2004 May, 5, (2): 89-97.
- (3) Tsitouras PD et al. "High omega-3 fat intake improves insulin sensitivity and reduces CRP and IL6, but does not affect other endocrine axes in healthy older adults." *Horm Metab Res*, 2008 Mar, 40 (3): 199-205.