

# Current Regulatory and Legal Context on “Modification of the Diet Alone”

Jessica P. O’Connell, JD, MPH  
Covington & Burling LLP  
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# Brief Definitional History

- “Medical Food” defined in 1988 amendments to Orphan Drug Act
  - a food which is formulated
    - to be consumed or administered enterally
    - under the supervision of a physician
  - and which is intended for the **specific dietary management of a disease or condition** for which **distinctive nutritional requirements**, based on recognized scientific principles, are established by medical evaluation
- Nutrition Labeling and Education Act (1990)
  - exempted medical foods from nutrition labeling, nutrient content claim, and health claim requirements

# Brief Definitional History

1993 FDA rulemaking to implement NLEA exemption

21 CFR 101.9(j)(8) - Food is subject to exemption only if:

- It is a specially formulated and processed product for the partial or exclusive enteral feeding of a patient;
- It is intended for the dietary management of a patient who 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 through dietary modification alone**;
- It provides nutritional support specifically modified for the management of **unique nutrient needs that result from the specific disease or condition**;
- It is intended to be used under medical supervision; and
- It is intended only for a patient receiving active and ongoing medical supervision

# Notable Differences

## Statute

Dietary management of disease or condition

“Distinctive Nutritional Requirement” established by medical evaluation

No mention of dietary modification

## Regulation

Dietary management of patient with limited capacity to ...

“Unique Nutrient Needs” that result from disease or condition

Dietary management cannot be achieved through dietary modification alone

# FDA Medical Food Warning Letters since 2006

No “Distinctive Nutritional Requirement” for the disease or condition

- Most WLs contain this charge, without qualification, for at least some products

No “Distinctive Nutritional Requirement” that **cannot be met through dietary modification alone**

- Some WLs since 2009 contain this charge: pregnancy, diabetes, bariatric surgery recovery
- Even if diet alone “*may not*” meet the distinctive nutritional requirement, still not medical food if no evidence that requirement “*cannot*” be met through dietary modification alone

# 2009 FDA Warning Letter: Neevo

- Medical Food marketed for
  - women under a physician's treatment for vitamin deficiency throughout pregnancy, postnatal and the lactating periods
  - older OB patients, high-risk pregnancies and OB patients with the methylenetetrahydrofolate reductase (MTHFR) folate polymorphism
- *While your website states that the patients for whom your product is intended have "distinct nutritional requirements" and implies that diet alone may not supply the full amount of nutrients necessary for women who are pregnant, planning to become pregnant, or are lactating, **there is no available evidence that the levels of folic acid and other micronutrients necessary for pregnancy or lactation cannot be achieved by the modification of the normal diet alone.** To the contrary, **it is not only possible, but practicable** for women who are pregnant, planning to become pregnant, or lactating to follow the IOM and FDA recommendations for folic acid intake within a normal diet. Specifically, given the widespread fortification of flours, breads, cereals, pastas, rice, and other grain products with folic acid as required by FDA regulations and the variety of available foods in which folic acid occurs naturally, **it would not be difficult** for a woman to consume up to 800 micrograms of folic acid per day (FDA's recommended daily folic acid consumption for pregnant women) through diet alone. Furthermore, folic acid **can be readily obtained from dietary supplements**, such as folic acid tablets and multivitamins containing folic acid.*

# FDA Medical Food DRAFT Guidance (Aug. 2013)

- **PREGNANCY**: *While a specific individual diet alone may not supply the full amount of nutrients necessary for women who are pregnant or planning to become pregnant, generally the levels of micronutrients necessary for pregnancy can be achieved by the modification of the normal diet alone. It is generally practicable for women who are pregnant or planning to become pregnant to follow the IOM and FDA recommendations for nutrient intake within a normal diet. Therefore, FDA generally would not consider a product labeled and marketed for pregnancy (rather than a specific disease or condition associated with pregnancy) to meet the regulatory criteria for a medical food.*
- **DIABETES**: *Diet therapy is the mainstay of diabetes management. A regular diet can be modified to meet the needs of an individual affected by either type of DM (along with appropriate drug therapy if necessary).*
- **CLASSICAL NUTRIENT DEFICIENCY DISEASES**: *The deficiencies, excluding any permanent physical damage, can typically be corrected once foods with these essential nutrients (or dietary supplements, if necessary) are made available and consumed. Because such diseases can typically be managed through dietary modification alone, FDA generally would not consider a product labeled and marketed for these diseases to meet the regulatory criteria for a medical food (see 21 CFR 101.9(j)(8)(iii)).*

# FDA Medical Food FINAL Guidance (Aug. 2013)

- **PREGNANCY**: There are **no distinctive nutritional requirements associated with pregnancy**. Essential nutrient requirements to support pregnancy can be met by diet modification.
- **DIABETES**: There are **no distinctive nutritional requirements associated with the management of DM**. Essential nutrient requirements for individuals affected by DM are no different than those for unaffected (generally healthy) persons. Following an individualized healthy, well-balanced diet is crucial to managing conditions such as DM. There are nutritional recommendations established for persons to manage DM.
- **CLASSICAL NUTRIENT DEFICIENCY DISEASES**: *Because such diseases can typically be managed through consumption of a healthy, well-balanced diet, FDA generally would not consider a product labeled and marketed for these diseases to meet the statutory and regulatory criteria for a medical food*
- *\*Change in language indicates effort by FDA to clearly tie “modification of diet alone” requirement to statutory requirement for distinctive nutritional requirement. In other words, FDA is interpreting “distinctive nutritional requirement” to mean a requirement that cannot be achieved through dietary modification alone.*