From Essentiality to Quality of Life:
Assessing “Distinctive Nutritional Requirements” in Different Clinical Contexts

MEDICAL FOODS WORKSHOP:
Science, Regulation and Practical Aspects
AUGUST 13–14, 2019 WASHINGTON, DC

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Modification of Diet Alone in the Context of Medical Foods

- "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." Orphan Drug Act
- "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;" 21 CFR 101.9(j)(8)(ii)

Origin of MoDA

- 1990 LSRO/FASEB report *Guidelines for Scientific Review of Enteral Food Products for Special Medical Purposes*
  - Defined medical foods as products that "demonstrate greater suitability for nutritional management of a specific disease than standard enteral formulas"
  - And are intended for "special medically determined nutrient requirements, the dietary management of whom cannot be achieved by the modification of the normal diet alone, by other foods for special dietary uses, or by a combination thereof."

Historical Context

- 1938 – FFDCA, amended 1941 to define “special dietary uses”
- 1957 – First approval for MF for inborn error of metabolism
- 1962-1972 – MF substantiation use same standard as for drugs
- 1972 – Most MF transitioned to/regulated as FSDU
- 1988 – Orphan Drug Act defines MF (now foods vs. drugs)
- 1990 – NLEA exempts MF from some labeling and claim requirements
- 1993 – MF defined in regulation at 21 CFR 101.9(j)(8)

Historical Context

- 1996 – FDA publishes MF ANPR for comment
- 2003 – FDA withdraws MF ANPR without comment
- 2007 – Draft MF guidance document published
- 2008 – MF Program Guidance Manual published
- 2013 – 2nd edition Draft MF guidance published
- 2013 – FDA Guidance: Determining whether human research can be conducted without an IND published
- 2016 – 2nd edition MF guidance finalized

FDA's Historical Perspective on Medical Foods

- Medical food category interpreted narrowly
  - Most patients with the target disease/condition would use them as major component of their diet under ongoing physician supervision
- MF: for individuals with distinctive nutrient requirements
- FSDU: for individuals who may have special nutrient needs but whose requirements can be met by modifying a normal diet
- 1996 ANPR – Concerns about potential misuse, product proliferation, QA controls, claim substantiation
- Limited statutory authority for regulatory oversight
- Minimal enforcement activity against MF

Questions

- Is MoDA really a single definable standard?
  - Historical focus: Technical feasibility
  - MANY other considerations impact one's ability to modify their diet
    - Palatability, expense, food preferences (personal and cultural), social aspects of food, presence of comorbidities, heterogeneity of disease severity (or etiology) within a given diagnosis, support systems, risk of failure, willingness to change, HCP "salesmanship", availability of needed foods, facilities to store/prepare food, QoL, patient burden, etc.
- Is the MoDA hurdle reasonable and fair?
- Does the MoDA requirement impede provision of optimal care?