



Food Advertising, Labeling, and Litigation Conference

*Medical Foods: Legal Factors,
Enforcement Actions and the Role of
Good Science*

Medical Food Definition

- Amendments to Orphan Drug Act (1988)
 - Congress established the medical food category in amendments to the Orphan Drug Act
 - Prior to 1988, FDA had informally permitted the marketing of a limited number of medical foods
 - A **medical food** is “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.” 21 U.S.C. § 360ee(b)(3).

Medical Food Definition (continued)

- Nutrition Labeling and Education Act (NLEA) (1990)
 - The NLEA exempted medical foods from nutrition labeling requirements, health claim restrictions, and nutrient content claim requirements
 - Nutrient based structure/function claims were permitted under the carve-out definition of drugs, as with all foods



Medical Food Definition (continued)

- NLEA implementing regulations (1993)
 - In order to fall within the medical food exemption from nutrition labeling, a food must:
 - Be a specially formulated and processed product for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;
 - Be 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;

Medical Food Definition (continued)

- Provide 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;
- Be intended to be used under medical supervision; and
- Be 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.

Medical Food Definition (continued)

- Advance Notice of Proposed Rulemaking (ANPR) (1996)
 - FDA sought comments as to how to interpret “distinctive nutritional requirement” in the medical food definition
 - Distinguished medical foods from foods for special dietary use by stating that “medical foods are foods that are an integral component of the clinical management of a patient” and not simply those recommended by a physician to lose weight or reduce disease risk



Medical Food Definition (continued)

- ANPR provided examples of currently available medical foods, including those intended for dietary management of:
 - Hypermetabolic states
 - HIV or other compromised immune function disorders
 - Diabetes mellitus
 - Malabsorption issues such as found in inflammatory bowel disease
 - Oral rehydration solutions
 - Phenylketonuria

Medical Food Definition (continued)

- ANPR did not concede that all product types listed in ANPR met the medical food definition
- FDA withdrew the ANPR in 2004 without addressing the many substantive comments
 - Stated it would continue to refer to principles described in ANPR when evaluating medical foods

Medical Food Definition (continued)

- FDA Guidance (2013)
 - Stated that the criteria in FDA's NLEA regulation “clarify the statutory definition of a medical food”
 - Medical foods are intended to be used under the active and ongoing medical supervision of a physician who has determined that the medical food is necessary
 - Not for diabetes mellitus, nutrient deficiencies, or pregnancy
 - Appropriate for patients with inborn errors of metabolism (IEMs)

Medical Food Definition (continued)

- Comments to 2013 Guidance
 - Various industry groups and stakeholders, including the Council for Responsible Nutrition, the American Society for Parenteral and Enteral Nutrition and the Academy of Nutrition and Dietetics, submitted comments to FDA's 2013 Guidance
 - Comments raised objections to FDA's interpretation of the medical foods definition; specifically, the NLEA exemption as creating additional requirements to qualify as a medical food, and disregard for possible interpretations of "distinctive nutritional requirements" proposed in the ANPR
 - Many comments also objected to the exclusion of diabetes as a disease or condition for which a medical food could be marketed
 - Other comments asserted that the interpretation stifled innovation, impeded the role of healthcare professionals in managing patient care and was an unlawful speech restriction in violation of the First Amendment

Medical Food Definition (continued)

- FDA Guidance (2016)
 - FDA issued a revised Guidance in 2016
 - Few changes from 2013 Guidance
 - Shift from discussing nutrient requirements for pregnancy, diabetes to stating explicitly that there are no “distinctive nutritional requirements” for such conditions
 - Only a handful of comments have been posted in response to the 2016 Guidance



INDs and Medical Foods

- FDA Guidance (2013) clarifies IND requirement for studies:
 - To evaluate a dietary supplement's or conventional food's ability to diagnose, cure, mitigate, treat, or prevent disease
 - To evaluate whether a food substance may reduce the risk of disease, intended to support a new or expanded health claim for foods or dietary supplements
 - To evaluate non-nutritional effects of a conventional food on the structure/function of the body
 - Studies to evaluate nutritional effects of food – including medical foods – do not require an IND
 - Note that a product must meet the definition of a medical food first to qualify (i.e., study cannot be attempting to prove the existence of distinctive nutritional requirements)

FDA Enforcement

- Spotty enforcement in recent years, but a couple warning letters were issued in 2016 and 2017
 - Targeted Medical Pharma, March 29, 2017
 - Company failed to submit an IND for clinical studies on its product, and claimed that the product was a medical food “used to treat the nutritional deficiencies associated with pain and inflammation”
 - FDA’s warning letter stated that there were no distinctive nutritional requirements for individuals with the condition that the protocols were designed to investigate (which was redacted in the warning letter), and therefore that the product was not a medical food under the statutory definition

FDA Enforcement (continued)

- Focus Laboratories, June 3, 2016
 - Company labeled and marketed Tozal Complete Eye Health Formula as a medical food for age-related macular degeneration
 - FDA determined that the product was not a medical food, referring to the “regulation in 21 C.F.R. 101.9(j)(8)” which “provides that a food is considered a medical food only if” it meets the regulatory requirements
 - Because FDA was “not aware of any distinctive nutritional requirements or unique nutrient needs for individuals with age related macular degeneration,” the letter stated that the “Tozal® product does not meet the regulatory criterion for medical foods set forth in 21 C.F.R. 101.9(j)(8)(ii)”



FDA Enforcement (continued)

- Earlier burst of letters in 2013
 - Accera, Inc., December 26, 2013
 - Product marketed as a medical food was intended for dietary management of “metabolic processes associated with mild to moderate Alzheimer’s disease”
 - Claimed to “enhance memory and cognition” and address “diminished cerebral glucose metabolism”
 - FDA determined that the product did not comply with the statutory definition of a medical food or with the regulatory requirements because “there are no distinctive nutritional requirements or unique nutrient needs for individuals with mild to moderate Alzheimer’s disease”

FDA Enforcement (continued)

– NVN Therapeutics, December 26, 2013

- “Glucorein PCOS” product was marketed as a medical food for individuals with “Polycystic Ovarian Syndrome,” and was represented to reduce “the incidence of metabolic syndrome and insulin resistance”
- Relying on both the statutory definition and the regulation at 21 C.F.R. 101.9(j)(8), FDA concluded Glucorein PCOS was not a medical food because there were “no distinctive nutritional requirements or unique nutrient needs for individuals with PCOS”

FDA Enforcement (continued)

– Realm Labs, LLC, April 11, 2013

- NeuRemedy products were marketed as medical foods for individuals with neuropathy to address low levels of thiamine
- FDA stated that it was “not aware of any evidence that patients with neuropathy have a limited or impaired capacity to ingest, digest, absorb, or metabolize thiamine, or other nutrients, or have a distinct requirement for thiamine or any other nutrient”
- Thus, the NeuRemedy products were not appropriately marketed as medical foods, according to FDA

Medical Food Products on the Market

- Companies are marketing medical foods for nutritional management of various diseases and conditions, including those which FDA has said do not fit the criteria for medical foods:
 - Diabetes
 - GI dysfunction
 - Chronic respiratory disease
 - Wound healing
 - COPD
 - Malabsorption or maldigestion
 - IEMs
 - Kidney failure

Best Practices for Developing a Medical Food

- A thorough process for developing medical foods provides a strong record to justify product positioning
- Create a standard operating procedure (SOP)
 - Understand FDA's framework for medical foods
 - Restrictive approach beyond statutory language
 - Be prepared with appropriate scientific support
 - Break down elements of medical food



Best Practices for Developing a Medical Food (continued)

- SOP (continued)
 - Conduct scientific literature review
 - Engage expert as needed
 - Draft a rationale or product support paper for the proposed medical food
 - Involve regulatory/legal team to ensure justification for medical food category
 - Consider creating a committee with representatives from multiple departments for final review of proposed medical food
 - As with all products, once medical food is approved, prepare substantiation file for any proposed claims

Key Science Considerations

- Distinctive nutritional requirements
 - Different analysis than for dietary supplements, foods for special dietary use
 - For those products, focus on safety, efficacy for intended use
 - Based on FDA's guidance and warning letters, the science underlying a medical food must demonstrate that the disease or condition has distinctive nutritional requirements that cannot be managed by modification of the normal diet alone
 - Show that management of the disease or condition can be achieved through specially formulated nutrition (including specific ingredients)



Key Science Considerations (continued)

- Conditions for which medical foods are appropriate
 - FDA has accepted only a limited number of conditions (e.g., IEMs) as appropriate for medical food use
 - Companies will need to support positioning in the medical food category with evidence that a medical food is integral to management of the disease or condition
 - Must be a medically identifiable disease or condition for which dietary management is appropriate
- Specially formulated
 - Medical food may not be a naturally occurring foodstuff in its natural state
 - Consider how to formulate, process product to achieve dietary management of disease or condition