2012 FDA Rare Disease Patient Advocacy Day

Regulation of Medical Foods

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Main Objectives

- History
- What is a Medical Food?
- What regulations and labeling requirements apply to medical foods

History

- Concept of specially formulated foods for seriously ill patients not new
- Special foods developed as early as 1940's
- FDA proposed first definition for Foods for Special Dietary Use (FSDU) in 1941

History

- Pre-1972, Lofenalac, was regulated as a drug
  - Role in mitigating serious adverse effects of underlying disease
  - Straightforward formulation
  - Under physician supervision ensured safe use
  - Scientific principles were clear with adequate testing for effectiveness

History

- Late 1972, removed from drug category to be regulated as an FSDU*—Why?
  - Usefulness widely accepted
  - Very limited in number
  - Increased time, expense and review with drug approval

  [*FSDU definition: 21 CFR § 105.3(a)]

History

- 1973-Preamble to the final rule on nutrition labeling (38 FR 2124 at 2126)
  - Exempted 2 types of FSDU from general requirements
  - “Medical Foods” came into being

History

- 1988-Orphan Drug Amendments created medical food definition

- "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))

History

- 1990 - Nutrition Labeling and Education Act
  - Incorporated the definition of medical foods (section 403(q)(5)(A)(iv) of the Federal Food, Drug and Cosmetic Act (21 U.S.C.343(q)(5)(A)(iv))
  - Exempted medical foods from nutrition labeling, health and nutrient content claim requirements
  - Identified five criteria to clarify characteristics of medical foods

Five criteria to clarify the characteristics of medical food (21 CFR 101.9(j)(8))

i. It is 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;

ii. 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;

Five criteria to clarify the characteristics of medical food (21 CFR 101.9(j)(8))

iii. 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;

iv. It is intended to be used under medical supervision; and

v. 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

History

- 1996-Regulation of Medical Foods: Advance Notice of Proposed Rulemaking (ANPR)
  - Clarification of definition of medical food
  - Substantiation of nutritional efficacy and claims
  - Questions asked for comment
  - Future directions

History

- 2003-Regulation of Medical Foods ANPR was withdrawn
  - Lack of activity, lack of resources, change in priorities
  - FDA opinions expressed are still the same

What is a Medical Food?

- The agency considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food (56 FR 60366 at 60377, November 27, 1991)

What is a Medical Food?

- Distinguishes from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision and intended for the specific dietary management of a disease or condition(56 FR 60366 at 60377, November 27, 1991)

What is a Medical Food?

- They are foods that are specially formulated and processed (as opposed to foods from a normal or conventional diet) for the patient who requires the product as a major management modality

- Does not pertain to all foods fed to sick patients

What regulations apply to medical foods?

- Medical foods are regulated, as are other foods, under the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) and the Fair Packaging and Labeling Act

- Under the Act, the manufacturer or distributor is responsible for ensuring that the food is not adulterated or misbranded

What regulations apply to medical foods?

- Under the Act, the medical food must comply with all applicable requirements for the manufacture of foods, including
  - Current Good Manufacturing Practices (21 CFR 110),
  - Registration of Food Facilities requirements (21 CFR part 1 Subpart H) and, if applicable,
  - the Low Acid Canned Food Regulations (21 CFR 113) and
  - Emergency Permit Control Regulations (21 CFR 108)

What regulations apply to medical foods?

- Ingredients used in medical foods must be approved food additives for their intended use or a food additive that is the subject of an exemption for investigational use (21 U.S.C. 321 and 348), if the ingredients are not Generally Recognized as Safe (GRAS)

What labeling requirements apply to medical foods?

- Medical foods must contain the following mandatory label information:
  - a statement of identity (the common or usual name of the product) (21 CFR 101.3),
  - an accurate statement of the net quantity of contents (21 CFR 101.105),
  - the name and place of business of the manufacturer, packer, or distributor (21 CFR 101.5), and
  - the complete list of ingredients, listed by their common or usual name, and in descending order of predominance by weight (21 CFR 101.4)

What labeling requirements apply to medical foods?

- All information required by the Act to appear on a food label must
  - appear with prominence and conspicuousness (21 CFR 101.15) and
  - be in English, and if a label bears any representation in a foreign language, then all mandatory label information must be repeated in each foreign language used on the label (21 CFR 101.15(c)(2))

Do medical foods have to be approved or registered with FDA?

- Medical foods do not undergo premarket review or approval by FDA

- Individual medical food products do not have to be registered with FDA; however, food facilities must be registered (21 CFR part 1 Subpart H)

Are medical foods manufacturing plants inspected?

- Yes, every other year unless the product is also intended for use as an infant formula—then the plant is inspected every year
- FDA has a Compliance Program that provides guidance to FDA Inspectors for the inspection of medical foods manufacturing plants

Future Directions

- Dependent upon . . . .
  - resources
  - priorities