2014 FDA/JIFSAN Food & Nutrition Webinar

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
  - Safe use ensured under physician supervision
  - Scientific principles were clear with adequate testing for effectiveness
History

September 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 process

[*FSDU definition: 21 CFR § 105.3(a)*]
1973 — Preamble to the final rule on nutrition labeling (58 FR 2124 at 2126)

- Exempted 2 types of FSDU from general requirements
- “Medical Foods” came into being
Statutory Definition

- 1988—Orphan Drug Act 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))
Nutrition Labeling and Education Act

- 1990 — Nutrition Labeling and Education Act
  - Exempted medical foods from nutrition labeling, health and nutrient content claim requirements
  - Identified five criteria to clarify characteristics of medical foods
Advance Notice of Proposed Rulemaking

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

- 2004 – Regulation of Medical Foods ANPRM was withdrawn
  - Lack of activity
  - Lack of resources
  - Change in priorities
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)
FSDU or 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)
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 (56 FR 60366 at 60377, November 27, 1991)

• Does not pertain to all foods fed to sick patients (56 FR 60366 at 60377)
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.
Food Manufacture Regulations

• 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)
Ingredient regulations

• Any ingredient added to a medical food should be:
  - a food additive used in accordance with FDA’s food additive regulations (see 21 CFR 172);
  - a color additive used in accordance with the color additive regulations (see 21 CFR 73 and 74);
  - a substance that is generally recognized, by qualified experts, to be safe under the conditions of its intended use (Generally Recognized As Safe, GRAS) (see 21 CFR 170.30 and 21 U.S.C. 321(s)); or
  - a substance that is authorized by a prior sanction issued by FDA (see 21 CFR 170.3(l)).
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)
Additional labeling requirements

• 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