

# DEVELOPING MEDICAL FOODS – POINTS TO CONSIDER

**NORD MEDICAL FOODS CONFERENCE**  
**Liaison Hotel, Washington, D.C.**

DIANE B. McCOLL  
Hyman, Phelps & McNamara, P.C.  
700 Thirteenth Street, N.W., Suite 1200  
Washington, D.C. 20005  
Telephone: 202-737-4291  
E-mail: [dmccoll@hpm.com](mailto:dmccoll@hpm.com)  
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# Points to Consider

- Meets Medical Food Definition?
  - Definition in Orphan Drug Act
  - FDA interpretation in nutrition labeling exemption
- Permissible Food Ingredients?
  - Approved food additive or GRAS use
- Food Use is Prohibited Act?

# Medical Foods

- A specially formulated and processed product for the partial or exclusive feeding of a patient by means of oral intake or perenteral feeding by tube.
- For dietary management of patients with special medically-determined nutrient requirements, that cannot be achieved by modification of the normal diet alone.
- Provides nutritional support specifically modified for the management of the unique nutrient needs.
- Only for use under medical supervision.

# Food Additives

- “. . . any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . .”

# Food Additives

- Prior FDA approval required; approval not exclusive.
- Subject to Delaney Clause:

“... no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.”
- Reasonable certainty in the minds of competent scientists that substance is not harmful under intended conditions of use.
- FDA approval takes years.

# GRAS Ingredients

- “Generally Recognized as Safe” (GRAS) Substances
  - [A] substance is . . . generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use . . .
- No FDA Premarket Approval Required.
- Use, Not Substance, is GRAS.

# Eligibility for GRAS Status

- GRAS Status Based on:
  - Common Use in Food Prior to January 1, 1958
  - Scientific Procedures
    - Technical Evidence of Safety
      - Conditions of intended use
      - Data, information, methods and application of scientific principles
    - Common Knowledge of Safety
      - Mere showing of safety is not sufficient; must be “generally recognized” as safe
      - Pivotal data and information in public domain

# FDCA § 301(II) Prohibition

- FDCA 301(II) prohibits addition of approved new drug or a licensed biologic to food.
- FDCA 301(II) also prohibits the addition to food of a drug or biological product for which:
  - substantial clinical investigations were instituted, and
  - existence of those investigations was public.
- No mention of IND.

# Exceptions to § 301(II) Prohibition

- First to Market Exception.
  - If approved drug or licensed biologic was first marketed in food, prohibition does not apply.
  - If drug or biological product for which substantial clinical investigations were instituted and their existence made public, was marketed in food before any such investigations were instituted, prohibition does not apply.

# Exceptions to § 301(II) Prohibition

- Prohibition does not apply if use of drug or biological product is:
  1. To “enhance the safety” of the food, and
  2. To not have independent biological or therapeutic effects on humans, and
  3. Conforms to one of the below:
    - a food additive or GRAS affirmation regulation;
    - a voluntary GRAS Notice prompting no FDA questions;
    - an effective FCN; or
    - marketed for smoking cessation prior to Sept. 27, 2007.
- FDA by rulemaking allows food use.

THANK YOU