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Enforcement, Litigation, and Compliance Conference

December 7-8, 2016
Washington, DC

Food: Medical Foods: FDA's Guidance, Substantiation Standards, and a Survey of Enforcement and Litigation Risk

William Garvin, Partner, Buchanan, Ingersoll & Rooney PC

Sarah Roller, Partner, Kelley Drye & Warren LLP

Moderated by: Brooke Schuum, President and Principal, Daneker, McIntire, Schumm, Prince, Manning, & Widmann, P.C.

“Medical Foods” – Regulatory Framework & Key Issues

Sarah Roller, JD, RD, MPH
Partner & Chair – Food & Drug Law Practice
Kelley Drye & Warren LLC – Washington, D.C.
December 7, 2016

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1938 FDCA – "Foods for Special Dietary Use"

- 1938 FDCA established the regulatory framework that allows "foods" to be represented for "special dietary uses"
- 403(j) permits foods to be "represented for special dietary uses" provided that
  - the "label bears such information concerning its vitamin, mineral, and other dietary properties [as FDA] determines to be, and by regulations prescribes as, necessary in order [to] fully inform purchasers as to its value for such uses"
- 403(a) and 201(n) requires all labeling to be truthful and not misleading, including through disclosure of "material facts"

FDA Implementing Regulations – "Foods for Special Dietary Use"

- "Special dietary uses" means foods that are specially formulated for use in subpopulations that have nutritional needs that are distinctive from those of the general population.
  - "The term 'special dietary uses, as applied to food for man, means particular (as distinguished from general) uses of food, as follows: . . . Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological, or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, under weight, and overweight."

1988 FDCA Amendments – "Medical Food" Definition

- With ODA Amendments, Congress recognized the need to encourage development of "medical foods" for the management of disease and health conditions
- Amendments define "medical food" as
  - [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

1990 FDCA Amendments

- The NLEA established requirements for nutrition labeling, nutrient content claims, and health claims
  - NLEA was intended to promote healthy dietary practices in the general population (e.g., in line with U.S. Dietary Guidelines for Americans)
- Amendments exempts "medical foods" from NLEA nutrition labeling and claims regimes
  - Exemption preserves FDA authority over FSDU for management of certain diseases and health related conditions affecting subpopulations
    - Exemption preserves FDA authority to establish labeling requirements for medical foods that are tailored to account for the distinctive labeling needs of purchasers and consumers of these products.

FDA Regulation Defining Scope of NLEA Exclusion

- FDA promulgated a rule implementing the NLEA exclusion
- The exclusion contains specific requirements that move beyond the statutory definition of "medical food" from the ODA Amendments –

> E.g., The food must 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"

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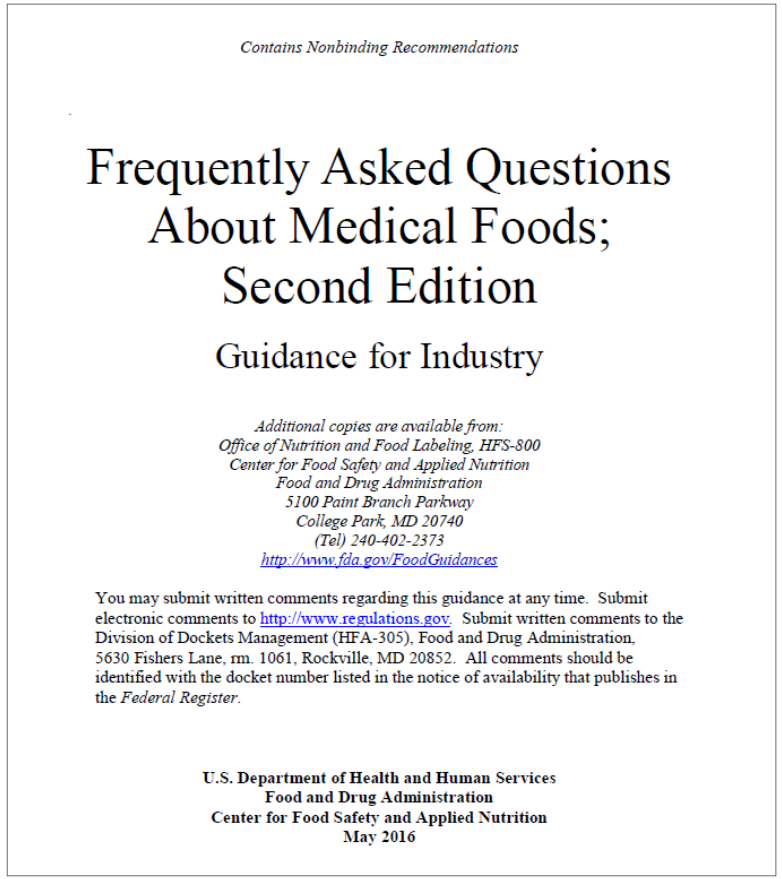
2016 FDA Guidance



Contains Nonbinding Recommendations

Frequently Asked Questions About Medical Foods; Second Edition

Guidance for Industry

Additional copies are available from:
Office of Nutrition and Food Labeling, HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
(Tel) 240-402-2373
http://www.fda.gov/FoodGuidances

You may submit written comments regarding this guidance at any time. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
May 2016

- Constricts category in ways not reflected in statutory definition
- Statute states “intended for specific dietary management of a disease or condition”
- Guidance, like regulation, adds that management of the distinctive nutritional requirement “cannot be achieved by the modification of diet alone”
- Guidance also adds new examples diabetes and pregnancy

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Practical Challenges of Overly Narrow Interpretation

- FDA's narrow interpretation of "medical foods" inappropriately subjects specialized products to the regulatory framework governing foods for the general population
  - FDA authorized "health claims" amount to disease-risk reduction claims.
  - Structure/Function claims for "foods" convey nutritional support for health and wellness.
  - Disease claims readily trigger regulation of foods as drugs.
- Current FDA policies impede the communication of truthful disease management claims for medical foods.

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First Amendment Considerations

- Failure to account for First Amendment protections of truthful commercial speech renders FDA's medical food labeling policies vulnerable to constitutional challenge
- A substantial body of relevant First Amendment case law firmly establishes FDA's constitutional obligation to implement FDCA requirements in a manner that accounts for First Amendment protections of truthful commercial speech.
  - Unduly restrictive FDA labeling policies found to interfere with the effective communication of relevant healthcare information to physicians and patients have been struck down on First Amendment grounds in recent cases.

Conclusions

- By updating FDA's policy to expand the medical foods category in line with the statutory definition as a "food" subcategory (distinct from a drug) and align labeling requirements with First Amendment and appropriate FDCA requirements (e.g., Sections 403(a) and (j)), FDA can better support the development and marketing of this important category of healthcare nutrition products

Questions?

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Medical Foods Current issues

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December 7, 2016

William A. Garvin

Buchanan, Ingersoll & Rooney PC

(202) 452 5471

william.garvin@bipc.com

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Overview

1. Background
2. FAQ Guidance
3. Rx only
4. NDC numbers
5. Warning Letters
6. Reimbursement

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Medical Foods Defined

- Orphan Drug Act – 1988 (21 U.S.C. § 360ee(b)(3), 5(b); FFDCA § 528)
  1. A food which is formulated to be consumed or administered enterally,
  2. Under the supervision of a physician,
  3. Intended for the specific dietary management of a disease or condition for which there are distinctive nutritional requirements established by medical evaluation, and
  4. Based on recognized scientific principles

  Note – No mention of requirement that medical food cannot treat a condition that can be treated through diet modification alone

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Nutrition Labeling and Education Act 1990

- Exempted medical foods from nutrition labeling, health and nutrient content claim requirements (21 U.S.C. § 343(q)(5)(A)(iv); FFDCA § 403)
- FDA implements regulations providing a five pronged definition for certain medical foods that are exempted (21 CFR § 101.9(j)(8))

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21 C.F.R. § 101.9(j)(8)

Medical food that meet the following definition are exempt from certain labeling requirements:

1. Specially formulated and processed for partial or exclusive feeding of patient orally or by enteral tube; and
2. Provides nutritional support to manage unique nutrient needs resulting from a specific disease/condition (per medical evaluation); and
3. Intended for use only under medical supervision; and
4. Intended only for patient receiving active/ongoing medical supervision; and
5. Intended for dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, 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.**

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After NLEA medical food regulation

- FDA issues notice regarding medical foods in 1996
  - Mentions that medical foods, which are for sick people, have less regulations than foods for healthy people
  - FDA withdrew this notice
  - Never passed regulations on medical foods
  - Never resolves questions asked in preamble
- Current status
  - Regulations implementing Nutrition Labeling and Education Act are the last ones dealing with medical foods
  - FDA filled vacuum by issuing a medical food compliance program guidance manual, Warning Letters against medical food products, and the Draft Medical Food Guidance issued in May 2007

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FAQ on Medical Foods

- Medical foods are not considered to be, or regulated as, drugs
- Thus no “Rx only” and no “NDC numbers” and no claims to reduce risk of disease

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Rx only

- Medical foods do not require a prescription and may not bear “Rx only”
  - This prohibition by FDA is not stated in the statute
  - FDA equates this statement to: “Caution: Federal law prohibits dispensing without prescription”
  - FDA said that it would not object to statements that convey message to consumers that it “must be used under the supervision of a physician”
  - But not clear where the line is (e.g., “Rx”, “dispense under prescription”, “dispense only under supervision of a physician”)
  - No other system to ensure physician supervision besides prescriptions.
- Objections
  - States complicate this (e.g., Florida Drug And Cosmetic Act 499.032 – “Phenylalanine restricted formula is declared to be a prescription drug”)
  - Could resolve with a disclaimer if necessary
  - Not allowing this truthful statement with disclaimer violates First Amendment
  - Legislative history does not support FDA’s position
  - How does FDA want to limit distribution
  - Prescriptions are necessary for proper use of medical foods and therefore Rx only is appropriate

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NDC numbers

- NDC numbers should not be used for medical foods
- NDCs are used to support
  - Billing
  - Reimbursement
  - Distribution
  - Recordkeeping
- Common objection - If not allowed to use NDCs, FDA should create new number for medical foods (e.g., National Medical Foods Code)
- Currently many companies use same number format without NDC description

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FDA Warning Letters

- Warning Letters
  - Metagenics – 2013
  - Realm Labs – 2013
  - NVN Therapeutics – 2013
  - Accera, Inc. – 2013
  - Focus Labs – 2016
- FDA stated that the following conditions couldn't be treated by medical foods:
  - Neuropathy, chronic fatigue syndrome, fibromyalgia, leaky gut syndrome, metabolic syndrome and cardiovascular disease, inflammatory bowel conditions and/or disease, Type 2 Diabetes, eczema, rhinitis and allergy-responsive asthma, bariatric patients pre- and post-operatively, Polycystic Ovarian Syndrome, peripheral artery disease, and Alzheimer's disease, macular degeneration

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Reimbursement

- Feds
  - No coverage for medical foods - “[M]edical foods do not meet the definition of a [covered outpatient drug].” - 81 Fed. Reg. 5170, 5189 (Feb. 1, 2016)
- States
  - Many states want to cover – Meeting with Medi-Cal
  - States may not reimburse all medical foods
  - States may define coverage different than Feds
- Drug listers
  - FDB (First DataBank) removing listing of medical foods from prescription listing and moving to “OTC”; Causing lack of coverage by private insurers
- Legislation needed for Federal coverage!!!

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Questions

William Garvin
(202) 452 5471
william.garvin@bipc.com

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