FDA Releases (an Updated) Guidance on Medical Foods: What They Are, And What They Are Not

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The Food and Drug Administration recently released its Second Edition of its "Guidance for Industry: Frequently Asked Questions About Medical Foods.[1]" The newer version updates previous guidance and provides responses to questions regarding the definition and labeling of medical foods and updates to some of the existing responses. While the guidance is not legally binding on FDA or industry, it offers insights into current agency thinking.

We note that the agency has issued Warning Letters in the past to companies purportedly selling medical foods, and many of FDA's statements and objections in those cases are reiterated here.

This Bulletin will describe briefly the definition of a medical food and summarize the guidance.

What is Medical Food?

The statutory and regulatory references to medical foods can be found at 21 U.S.C. § 360ee(b)(3) and 21 C.F.R. § 101.9(j)(B).

- A medical food is defined 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." A medical food is not a drug.

- Medical foods are a distinct group that are 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.

- Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition, and all foods fed to sick patients are not medical foods.

- Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who is seriously ill or who requires use of the product as a major component of a disease or condition's specific dietary management.

Labeling

- A medical food is exempt from FDA's nutrition labeling requirements if:
  - It is a 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.[2]

1 See www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm054048.htm. (May 2016).
2 FDA explains this route of administration to mean a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine.

- 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.
- 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.
- It is intended to be used under medical supervision.
- 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.

- Medical foods are exempt from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990.

- The labeling of medical foods must contain:
  - a statement of identity
  - an accurate statement of the net quantity of contents
  - the name and place of business of the manufacturer, packer, or distributor
  - a complete list of ingredients, listed by their common or usual name and in descending order of predominance

- A medical food may not make a false or misleading claim, i.e., cannot be misbranded.

Other Requirements

- Manufacturers of medical foods must comply with all FDA requirements for foods such as, but not limited to, current good manufacturing practices and registration of food facilities.

- An ingredient that is added to a medical food should be safe and comply with all applicable FDA rules.

- Any ingredient added to a medical food should be: (1) a food additive used in accordance with FDA's food additive regulations; (2) a color additive used in accordance with the color additive regulations; (3) a substance that is generally recognized, by qualified experts, to be safe under the conditions of its intended use (generally recognized as safe (GRAS)); or (4) a substance that is authorized by a prior sanction.

- FDA does not maintain a comprehensive list of medical food products.

FDA Comments

- Medical foods must be formulated to be consumed or administered enterally under the supervision of a physician, but there is no requirement for a prescription.

- FDA explains that supervision of a physician means that the intended use of a medical food is for the dietary management of a patient receiving active and ongoing medical supervision (e.g., in a health care facility or as an outpatient) by a physician who has determined that the medical food is necessary to the patient's overall and ongoing medical care.

- The labeling of medical foods may not bear the symbol "Rx only."

- However, because medical foods are required to be used under the supervision of a physician, FDA will not object to language that communicates this requirement (e.g., "must be used under the supervision of a physician").

- The labeling of medical foods should not include NDC numbers; the presence of an NDC number on a food product that is not a drug misbrands the product, and any representation that creates an impression of official FDA approval through the use of an NDC number in labeling constitutes misbranding.

Some Specific Examples Cited by FDA

- FDA generally considers inborn errors of metabolism (IEMs) to be diseases or conditions that a medical food could be used to manage.

- FDA does not consider pregnancy to be a disease; there are no distinctive nutritional requirements associated with pregnancy, and essential nutrient requirements to support pregnancy can be met by diet modification.

- There are no distinctive nutritional requirements associated with the management of diabetes mellitus, so a product with this claim would likely not qualify as a medical food.

- Diseases (e.g., scurvy, pellagra) that result from essential nutrient deficiencies (e.g., deficiencies of vitamin C, niacin) are primarily caused by inadequate intake (e.g., famine, significant calorie restriction, eating disorders, alcoholism, diet practices/fad diets). Because such diseases can typically be managed through consumption of a healthy, well-balanced diet, FDA would not generally consider a product labeled and marketed for these diseases to qualify as a medical food.

- Conventional foods that do not ordinarily contain protein or are ordinarily low in protein would not meet the criteria for medical foods.

It should be noted that FDA's previous 2013 draft guidance received considerable comment from industry, who argued that the agency's definition and application of the medical foods criteria was overly restrictive. In general, FDA did not respond favorably to these comments.

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