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FDA Serves Up Another Helping of Draft Guidance on Medical Foods

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On August 13th, the Food and Drug Administration (FDA) released a second version of its draft guidance on medical foods. The draft guidance, "**Frequently Asked Questions About Medical Foods; Second Edition**," amends and expands upon the original draft guidance published in 2007 by incorporating 15 new questions and answers. Specifically, the FDA addresses medical food labeling, physician supervision, and the scope of permissible diseases or conditions that medical foods may be labeled or marketed to manage.

A "medical food" is defined in the **Orphan Drug Act** 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." In accordance with the 2007 draft guidance and several recent Warning Letters, the revised draft guidance advises that it considers the statutory definition to "narrowly constrain" this category of food. The FDA has also provided criteria clarifying the statutory definition of medical foods in its regulations. ***See* 21 C.F.R. § 101.9(j)(8)**. Products that qualify as medical foods are exempt from nutrition labeling requirements, as well as the requirements for health and nutrient content claims. Accordingly, medical foods may bear claims regarding the management of disease or meeting the distinctive nutritional requirements of disease patients.

The pivotal aspects of the draft guidance are discussed below.

Medical Food Definition

The 2007 draft guidance described medical foods as foods that are "specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for the patient who is seriously ill or who requires the use of the product as a major treatment modality." The revised draft guidance replaces the technical term "treatment modality" with the phrase "component of a disease or condition's specific dietary management." This revision signifies the FDA's growing emphasis on the idea that a medical food must be designed for dietary management of a disease condition, rather than generalized treatment.

Qualifying Disease or Condition

Medical foods cannot be labeled or marketed for a disease or condition that can be *managed solely by a normal diet alone*. Such conditions or diseases discussed specifically in the draft guidance include Inborn Errors of Metabolism (IEMs), Pregnancy, Diabetes Mellitus (Types 1 and 2), and Nutrient Deficiency Diseases.

Inborn Errors of Metabolism (IEMs)

IEMs, which include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate, are generally considered to be diseases or conditions that a medical food may be used to manage. Some IEMs can be managed solely with modification to the *normal* diet (*e.g.*, reduction of galactose and lactose for galactosemia), but others cannot. For those IEMs that cannot be managed solely with modification to the normal diet, a medical food is required in addition to a specific dietary modification (e.g., reduced total protein/phenylalanine for phenylketonuria). The draft guidance provides a non-exclusive list of specific IEMs that medical foods could be used to manage.

Pregnancy

The FDA does not consider pregnancy a disease, instead agreeing with the Institute of Medicine that it is a "life stage." The agency also does not consider pregnancy to be a condition for which a medical food could be labeled or marketed. The draft guidance explains that "generally the levels of micronutrients necessary for pregnancy can be achieved by the modification of the normal diet alone."

Diabetes Mellitus (DM) Types 1 and 2

The FDA does not generally consider a product labeled and marketed for DM to meet the regulatory criteria for a medical food, based on the theory that "diet therapy is the mainstay of diabetes treatment." The agency provides that a regular diet can be modified to meet the needs of a person with DM (along with appropriate drug therapy, if necessary).

Nutrient Deficiency Diseases

The agency does not consider classical nutrient deficiency disease, like scurvy or pellagra, to be diseases for which a medical food could be labeled and marketed. Excluding any permanent physical damage, such diseases can typically be corrected once foods (or dietary supplements) with these essential nutrients are consumed. In short, nutrient deficiency disease can be managed by normal diet alone.

Physician Supervision

The draft guidance emphasizes that no written or oral prescription is necessary for medical foods. However, the FDA does not consider foods that are simply recommended by a physician or other health care professional as part of an overall diet designed to reduce the risk of a disease or medical condition or to help support weight loss to be medical foods. Rather, the statutory requirements that a medical food be consumed or administered enterally "under the supervision of a physician" mean 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) of a physician who has determined that the medical food is necessary to the patient's overall medical care." The FDA now expects that the patient should generally see the physician on a recurring basis for, among other things, instructions on the use of the medical food.

Food Facility Registration

Just like any other domestic or foreign food facility, a facility that manufactures, processes, packs or holds medical foods for consumption in the U.S. must register with the FDA.

Labeling

According to the draft guidance, medical foods will be misbranded if their labeling bears the symbol "Rx only" and/or National Drug Code (NDC) numbers. However, the FDA does not object to the use of language communicating that the medical food may only be distributed enterally under the supervision of a physician. The FDA provides the following example: "must be used under the supervision of a physician."

Conclusion

While the revised draft guidance is no doubt intended to shed light on the FDA's regulation of medical food, some of the FDA's answers are likely to engender fervent industry commentary. Pursuant to the Federal Register Notice, all comments on the draft guidance should be submitted by October 15, 2013 to ensure consideration by the FDA before it begins work on the final version.

To explore how the draft guidance could potentially affect your business, please contact **David Adams**, **Todd Harrison**, **Claudia Lewis**, **Ralph Tyler**, **Michelle Jackson**, **John Moore**, or **Erin Seder**.

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