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Medical Foods: A Distinct Class of Therapeutic Agents

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Overview

Prescription drugs are widely appreciated by both physicians and patients alike as important weapons in the treatment of human disease. In contrast, the increasingly important and often complementary category of therapeutic agents known as medical foods remains a largely misunderstood component of today's healthcare armamentarium. Moreover, despite being governed by the Food and Drug Administration (FDA), there remains much confusion as to what is required to bring a medical food to market. In this brief communication, we will take a look at the history of medical foods, how they are distinguished from drugs and nutritional supplements, and the FDA rules under which they must be developed and used.

Medical foods must meet the distinctive nutritional requirements or metabolic deficiencies of a particular disease state, are formulated to be consumed or administered under the supervision of a physician, and contain ingredients that are generally recognized as safe (GRAS) [1]. Medical foods are meant to be an integral part of an overall disease management plan [1,2].

Evolution of Medical Foods as a Distinct Class of Therapeutic Agents

Prior to 1972, the FDA regulated medical foods that mitigated serious adverse effects of an underlying disease as drugs under the Federal Food, Drug, and Cosmetic Act. In 1972, in an effort to encourage innovation and availability of such products, the FDA revised its regulatory approach and classified these products as "foods for special dietary use" [1,3].

The Orphan Drug Amendments of 1988, Section 5b, Orphan Drug Act (21 U.S.C. 360ee (b) (3)) [4], defined 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." The current legal definition of medical foods provided above dates to the Orphan Drug Act of 1988. In addition to defining medical foods, the Act introduced a subcategory called orphan medical foods to be used in the management of "…any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such a disease or condition will be developed without assistance" [5]. This is similar to the provision that applied to drugs in the original

Orphans Drug Act of 1973, to ease normally required development costs for those drugs (orphan drugs) not anticipated to return development costs due to minimal need for rare diseases [6]. However, there are no developmental regulations for medical foods that would require the creation of an orphan category [7].

In the Nutrition Labeling and Education Act of 1990 [8], Congress exempted medical foods from the nutrition labeling, health claim, and nutrient disclosure requirements as long as the medical food met certain requirements. In contrast, under the 1990 amendments, medical foods are specifically exempted from the requirements for nutrition labeling, nutrient content claims, and health claims." The definition of a medical food was restated in the FDA's Final Rule on Mandatory Nutritional Labeling, January, 1993 [9]. Specifically, a product classified as a medical food must meet the following requirements:

- It is a specially formulated and processed product (as opposed to a naturally occurring food stuff used in its natural state).
- It must be consumed or administered enterally, either by ingestion or intragastric tube.
- 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.
- The nutritional need could not reasonably be supplied by dietary alteration alone.
- It is intended to be used under medical supervision (i.e., by prescription).
- It is intended only for a subject receiving active and ongoing medical supervision wherein the subject requires medical care on a recurring basis, i.e., medical foods are intended for a diseased population.
- It is composed of ingredients designated as GRAS.
- It is based on recognized scientific principles.

Further, according to the proposed rules for medical foods published in the Federal Register in 1996 [10], "Foods for special dietary use are subject to the same nutrition labeling requirements and requirements for health claims and nutrient content claims established for most other foods by 1990 amendments. Thus, foods for special dietary use, like ordinary foods, must be labeled with certain nutrition information in a prescribed format to ensure that such information is presented in an informative and understandable fashion. Moreover, any nutrient content claims or health claims on the label or in the labeling of a food for special dietary use must have been authorized by FDA to ensure that the claim is scientifically valid and is presented in such a way that it is truthful and not misleading."

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A recent FDA guidance states that an Investigational New Drug

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Regulatory	Drugs	Medical Foods	Dietary Supplements
Manufactured under cGMP	Yes	Yes	Yes
IND required	Yes	No	No (Needed for health claims)
Pre-market scientific testing	Preclinical and clinical studies (phases I, II, III)	Medical evaluation in patients with the specific disease being targeted	No
NDA/BLA required	Yes	No	No
Claims permitted	Negotiated with the FDA and dependent on pivotal clinical trial data	Dietary management of a specific disease	Support healthy function
Intended treatment population	Diseased	Diseased	Healthy
Safety and pharmacovigilance	Need to establish through clinical trials and post market surveillance	GRAS and post market surveillance	General expectation of safety and through monitoring of consumer complaints
Physician supervision	Required if prescription drug not for OTC medications	Required	None

Table 1: Therapeutic Agents: Differences Between Drugs, Medical Foods, and Dietary Supplements.

(IND) is only required for all new drugs under investigation, as well as foods and dietary supplements that are intended to evaluate the dietary supplements ability to diagnose, cure, mitigate, treat, or prevent a disease [11]. This guidance does not apply to medical foods, which are designed for dietary management of a disease. Unlike drugs, medical foods are not developed under IND procedures, or licensed under New Drug Application (NDA) requirements, but are subject to a specific set of governing regulations of their own [12]. Therefore, institutional review boards do not have to, and in fact, should not, ask manufactures to obtain either an IND or a waiver from the FDA in order to conduct clinical studies for the development of a medical food. Obtaining an IND for a food product would preclude the ability to develop it as a medical food; it would then be classified as a drug and be subject to all IND regulations [11].

Medical foods are not approved by the FDA in the same manner as drugs, but are required to support all claims with good laboratory and clinical science. Medical foods are required to be manufactured under Current Good Manufacturing Practices conditions. Drugs and medical foods, unlike dietary supplements, can be labeled for medical conditions, such as inflammatory bowel disease.

Safety and Efficacy of Medical Foods

The safety of medical foods is ensured by the requirement that all ingredients be either approved food additives or classified as GRAS. As with any therapeutic treatment, serious adverse events are to be reported to the FDA. While medical foods are not required to submit for pre-market approval or review by FDA, disease claims for medical foods must be based on recognized scientific principles and need to be substantiated by substantial scientific evidence. Products may contain specific nutrients or natural products that would allow the patient to return to a metabolic or physiological homeostasis that was in disequilibrium due to disease [12].

The differences between the 3 classes of therapeutic agents (drugs, medical foods, and dietary supplements) are summarized in Table 1.

Conclusions

Medical foods are a distinct class of FDA-regulated therapeutic agents that meet the distinctive nutritional requirements or metabolic deficiencies of a particular disease state, are formulated to be consumed or administered under the supervision of a physician, and contain ingredients that are generally recognized as safe (GRAS). Clinical trials are a frequent part of the development of a medical food but they are not conducted under an IND. Medical foods are designed to be a component of an overall disease management plan which are administered under physician supervision.

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