

## Medical Foods—A Unique FDA Product Category (for Aloe Today, Fall 2004 issue)

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The Food and Drug Administration (FDA) has created a unique category of product for the *nutritional* medical management of a disease or disease condition. Medical foods constitute a narrow category of products, somewhere between conventional foods and pre-approved drugs that are intended to address the “distinctive nutritional requirements” of a particular disease. Unlike a dietary supplement, a medical food is intended for use under medical supervision, and for a particular disease or dietary condition, and may be the sole food of a patient’s diet, e.g., for a terminally ill AIDS patient with special nutritional needs who cannot consume or digest ordinary food. Other examples are: special infant formulas, formulations for metabolic disorders, oral rehydration products or products for chronic diarrhea, and special nutritional formulas for patients with diabetes or kidney disease. A classic type of medical food would be a special formulation of amino acids and proteins to meet the distinctive nutritional requirements of burn or wound victims, necessary to heal the skin or to grow new skin. Medical foods are typically in the form of liquids or powdered drink mixes, but there is no statute or regulation forbidding or precluding pill or capsule form. They are used both in hospitals and in the home, but in either case their use must be supervised by a physician.

The threshold requirement for a medical food is that it be for a disease with distinctive nutritional needs or metabolic deficiencies, and be medically shown to meet those needs. The second requirement is that the medical food provide nutrition administered “enterally.” This means that it is taken by mouth and travels to the gastrointestinal tract, or it is administered through a tube, taking the nutrients directly to the stomach or small intestine.

So far, a medical food is beginning to sound like a drug, but, it is neither a prescription drug nor an over-the-counter (OTC) drug, and thus it does not require FDA approval of its safety and efficacy before it may be marketed. However, a medical food is intended for a patient receiving medical supervision in the course of managing a disease or a condition with specific nutritional requirements, and it must be labeled as such. Also, all medical foods ingredients must have a guarantee of safety called GRAS status, for Generally Recognized As Safe.

"Medical food" is defined, by statute, at 21 U.S.C. § 360ee(b)(3) as "a food -- which is formulated to be consumed or administered enterally [by mouth]-- under the supervision of a physician -- and which is intended -- for the specific management of a disease or condition -- for which distinctive nutritional requirements -- based on scientific principles -- are established by medical evaluation." I separated each of the elements of the definition by a dash (--) for convenience in focusing on the individual components of this statutory definition. This definition is incorporated by 21 C.F.R. § 101.9(j)(8)(i)-(v), the FDA's nutrition information regulation. That regulation exempts medical foods from the nutrition labeling requirements (e.g., the Nutrition Facts box) which are, except for dietary supplements, applicable to all other foods.

The next logical question is: What sorts of claims are permissible for medical foods, and what level of substantiation is required for these claims? Specific claims may be made about exactly how the medical food product meets the distinctive nutritional requirements of a disease or condition. However, the need for the product must be medically established, the product must be formulated based on sound science, and the claims for efficacy or effectiveness must be based on scientific evidence. Neither medical foods nor the claims made for them require premarket approval from the FDA, and no substantiation standard has been set for medical foods claims. Most probably, the substantiation should be stronger than the “significant scientific agreement” standard used for unqualified health claims, but it need not be as rigorous as the “substantial evidence” standard (supported by human clinical trials) required for drugs.

A common mistake made by those not completely familiar with medical foods is to confuse them with dietary supplements, perhaps because both types of products contain nutritional ingredients such as vitamins, minerals, and herbs. However, medical foods and dietary supplements are not interchangeable, and this mistake could even result in regulatory or legal liabilities to the party in error. First, these are discrete regulatory classifications, with a specific statutory definition for medical foods, within the Orphan Drug Act, and an entire long statute, the Dietary Supplement Health and Education Act (DSHEA), for supplements. Second, medical foods must be first be shown, by medical evaluation, to meet the distinctive nutritional needs of a particular patient population before they may be marketed, whereas supplements are intended for normal, healthy adults and require no efficacy tests pre-market. Third, medical foods may be the sole nutrient or food of a patient group, e.g., terminal AIDS patients, whereas supplements may not be a meal or meal replacement. Fourth, medical foods require physician supervision (and thus institutional administration or a prescription or close outpatient monitoring) whereas dietary supplements are self-administered by the consumer. Fifth, medical foods are specially formulated for a diseased patient population whereas dietary supplements are intended for a healthy consumer population. Sixth, medical foods make medical claims (i.e., to manage the disease) whereas dietary supplements make structure/function claims (i.e., to support the healthy function of the particular body part or process) and are forbidden to make disease claims. Seventh, supplements as well as conventional foods are eligible to make certain health claims (FDA pre-approved claims that a substance prevents or lowers the risk of a disease), whereas medical foods are not eligible, given that they are intended for dietary management of an *existing* disease. Eighth, while dietary supplements are governed by meticulous labeling requirements, including a detailed Supplement Facts box, there are virtually no labeling regulations for medical foods except for the statement “must be administered under physician supervision.” Thus, these categories of products are regulated and enforced separately: one is a medical product and the other is a consumer product.

Finally, in addition to having a medical purpose, as opposed to simply supplementing the diet and maintaining good health and normal functions, a medical food has very different labeling requirements from a dietary supplement, and indeed many non-requirements. If a product meets the legal definition of “medical food” then it is exempted from the nutritional labeling regulations for conventional foods in 21 CFR § 101.9. This means that there is no set of regulations governing the label or packaging for medical foods, as distinct from conventional foods and dietary supplements. However, I usually recommend that the label contain the mandatory information that all food labels must bear, e.g., statement of identity (MEDICAL FOOD), net contents, and name and address of manufacturer. Most important, the label must state that the product is to be taken under the supervision of a physician. Indeed, medical foods must be clearly packaged and advertised as “for the dietary management of \_\_\_\_\_,” a specific disease. As has been shown in two recent FDA Warning Letters, labels stating or implying that the product is for the treatment of disease mark that product as a drug, rather than as a medical food, and thus will be considered an unapproved new drug by the FDA.

Ironically, given that medical foods are intended for ill and vulnerable patient populations (as opposed to normal healthy adults), there is no guidance from the FDA on the listing of ingredients for a medical food. There is no regulation comparable to those for the Nutrition Facts box or the Supplement Facts box, and thus technically a complete list of each nutritional ingredient and its amount are not required. However, pursuant to the FDA's general principles, the ingredient listing must be readable and understandable to the consumer. My recommendation is that there be a "Each Serving Contains" including all the major nutritional ingredients, and their amounts, and also the total amount of any proprietary blends. The main criteria for the label according to the FDA is: Is it false or misleading to the consumer? Finally, there are no regulations—from either the FDA or the FTC, the Federal Trade Commission—covering advertisements for medical foods, most of which are marketed to and through physicians.

**\*This column is not meant, and should not be construed, as a legal opinion, or legal advice, but rather is intended to provide general principles and some examples as to various aspects of FDA law.**

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