



## PIC QUESTION OF THE WEEK: 4/21/08

Q: What is the definition of a *medical food*?

A: The term *medical food* was first defined by the Food and Drug Administration (FDA) in the 1988 amendment to the Orphan Drug Act. Medical foods are a class of products that are consumed or administered to meet a specific dietary requirement resulting from a disease or condition. The FDA has established a number of criteria that must be present to designate a formulation as a medical food. The product:

- must be intended for oral use or administered through an enteral feeding tube
- is intended for the dietary management of a patient who, due to medical conditions, cannot meet their nutritional requirements
- provides nutritional support for a specific need caused by a specific medical condition
- is used under medical supervision, and
- is intended only for patients receiving active and ongoing medical care

The FDA requires that medical foods be formulated based on scientific evidence. They do not, however, have to be evaluated in clinical trials for safety or efficacy prior to marketing. The products may be distributed as tablets, capsules, or liquid dosage forms. Medical foods are similar to dietary supplements in that they do not require a prescription (some may have an  $R_x$  symbol on the package). However, unlike dietary supplements, medical foods are permitted to be labeled for the management of *specific* medical conditions. For example, Limbrel is labeled for the management of osteoarthritis. Other examples of medical foods include cerefolinNAC (memory improvement), UltraMeal (metabolic syndrome), VSL#3 (ulcerative colitis), Deplin (augmentation of antidepressants), Phenyl-Free-1 (phenylketonuria in infants and toddlers), Pro-Phree (celiac disease), Ketonex-1 (maple syrup urine disease), and Fosteum, a capsule containing cholecalciferol, zinc chelate, and genistein – a phytoestrogen - that is indicated for osteoporosis. Medical foods are a little known, but increasingly used, class of healthcare products.

### References:

- Mueller, C. The regulatory status of medical foods and dietary supplements in the United States. *Nutrition* 1999;15:249-51.
- Food and Drug Administration. Frequently asked questions about medical foods. <http://www.cfsan.fda.gov/guidance.html>. (accessed April 16, 2008).
- Medical Food: Limbrel. *Pharmacist's Letter/Prescriber's Letter* 2005;21(5):210515.

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