



UNDERSTANDING NUTRACEUTICALS

How They Differ from Health Store Supplements

by Linda Sechrist

Savvy consumers seeking products that might help them achieve and maintain good health may be noticing two new categories: medical food and nutraceuticals.

Medicalized terminology is now being used to describe certain products we may already have been buying from brand-name dietary supplement companies and retailers, and they have a higher price tag. One common example: powdered protein meal-replacement shakes that can cost up to \$16 more than a retail store brand, as nutraceutical and medical food purveyors want to differentiate their products as having clinical research and development behind them. This raises the bar on the quality of contents and assures consumers of third-party testing for proof of ingredients.

Although both are regulated under the Dietary Supplement Health and

Education Act (DSHEA) of 1994, there is no legal distinction between dietary supplements and nutraceuticals, yet each serves different purposes. Dietary supplements, comprising vitamins, minerals and/or herbs and botanicals, are intended to enhance wellness among healthy adults.

Nutraceuticals encompass nutrients, foods or parts of foods used as medicine to provide health benefits beyond nutrition and combat chronic disease. Some of the most popular formulations involve botanicals like ginseng, ginkgo biloba, St. John's wort and echinacea.

“Medical foods, formulated for dietary management of a specific medical condition for which nutritional needs are unmet by a normal diet, are regulated under

the Orphan Drug Act of 1983,” explains Bill Shaddle, senior director of medical education at Metagenics, Inc. “Our nutraceuticals and medical foods are supported by verifiable science that provides solid evidence regarding the therapeutic benefits produced by ingredients in our products.”

The word nutraceutical, blending nutrition and pharmaceuticals, was coined in 1989 by Stephen L. DeFelice, the founder and chairman of the nonprofit Foundation for Innovation in Medicine, in Mountainside, New Jersey, which promotes clinical research and development of dietary supplements and foods specifically for their health benefits.

Reputable companies that manufacture private-label nutraceuticals, such as Metagenics and Xymogen, among others, research and develop products for functional nutrition and quality. While such products are solely distributed through partnerships with healthcare professionals such as medical doctors, nutritionists and pharmacists, some of the evidence-based, professional-grade formulas are available through online physician websites.

Metagenics and Xymogen collaborate with institutions such as the Cleveland Clinic, Bastyr University and National College of Natural Medicine in conducting clinical research that demonstrates how their formulas impact healthy aging, cognitive function and overall health.

Federal Regulations

Medical foods and nutraceuticals, orally administered dietary products formulated to support the management of conditions such as compromised gut function, age-related muscle loss, metabolic syndrome, Type 2 diabetes and cardiovascular disease, are subject to standard food and safety labeling requirements of the *Federal Food, Drug and Cosmetic Act*. Although they may be used under medical supervision, patients don't need a prescription. Many healthcare practitioners, including dietitians, currently recommend them under a physician's direction.

Unlike pharmaceuticals, which are accountable to the Food and Drug Administration's Center for Drug Evaluation and Research, patent-protected and supported by expensive testing documentation, nutraceuticals are not. However, many manufacturers

do choose to undergo costly testing. Like all dietary supplements, the majority of which do not undergo third-party testing, they are regulated by DSHEA, which defines and regulates labeling and claims of benefits related to classic nutrient-deficiency diseases.

Private Quality Control

Xymogen is strictly a physician's line of nutraceuticals, explains Cheryl Burdette, a doctor of naturopathy and director of clinical research and outreach for the company. "In our manufacturing process, to avoid contamination and validate ingredients, every batch is third-party assayed by an independent laboratory, whereas some companies only do this for every fifth or 20th lot. Xymogen's validation extends to packaging and controlling the level of humidity because it affects how ingredients oxidize," says Burdette.

Gary Kracoff, a registered pharmacist and naturopathic doctor at Johnson Compounding & Wellness, in Waltham, Massachusetts, researches the nutraceuticals that he carries and recommends for his clients. "I like professional-grade nutraceuticals

because their formulas are researched and science-based. They are excellent products for specific purposes. Individuals that take the medical foods come to appreciate their disease-modifying therapeutic results. While pricier, they include healthier sources of carbohydrates and fats, as well as natural, rather than synthetic nutrients to provide what the body needs to return to a state of balance," says Kracoff.

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