

DIETARY SUPPLEMENTS

Overview

Congress defined the term “dietary supplement” in the Dietary Supplement Health and Education Act (DSHEA) of 1994 as ‘a product taken by mouth that contains a dietary ingredient intended to supplement the diet. The dietary ingredients in these products include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandular substances, and metabolites. Dietary supplements can also be extracts or concentrates, and are found in forms such as tablets, capsules, soft gels, gel caps, liquids, and powders. They can also be in food forms, such as bars and juices, but labeling of such products must not represent the product as a conventional food or a sole item of a meal or diet. In addition, DSHEA requires that every supplement be labeled clearly as a dietary supplement. Thus, according to DSHEA, dietary supplements are regulated by a specific regulatory category and are enforced by the Center for Food Safety and Applied Nutrition (CFSAN) under the US Food and Drug Administration (FDA), not the Center for Drug Evaluation and Research.

Dietary supplementation has become a popular alternative to traditional medicine because of high health care costs, a larger aging population, and a faster, more stressed-out pace of life. Optimally, nutritional supplements can contribute to a more positive lifestyle and improved quality of health. Although dietary supplements have become popular in recent times, you may be asking yourself, “What are the potential dangers in taking these products? Do they actually contain what the label purports? What is the source of the supplement, and how is it produced to ensure that you are not receiving toxic ingredients? What are the safe levels of ingestion?” Since dietary supplements are regulated as food instead of as drugs, they do not have to be approved for effectiveness or safety by the Food and Drug Administration (FDA) before products are distributed.

Stemming from years of outcry by consumers and health professionals alike, the FDA, in 2003, proposed the use of a standard called “Good Manufacturing Practices” (**GMP**). These standards define methods, equipment, facilities and controls for ensuring quality. These GMPs are intended to ensure that the products meet label content claims and that manufacturers use safe, quality means, free of contamination. They still will not ensure the efficacy of a product (that it performs as claimed). Presently, appropriate methods are not available for testing all dietary supplements.

Supplement Verification

Undertaking the challenge of protecting the consumer from poorly formulated, false, or even toxic “dietary supplements” is a huge task. Manufacturers of dietary supplements worldwide do have access to voluntary scrutiny by the United States Pharmacopeia (**USP**). A verification label by USP on a product indicates that it not only meets GMP, but contains ingredients that will release and dissolve so as to be available for absorption as intended and contains ingredients in the amounts stated. The U.S. Pharmacopeia is the official public standards-setting authority for all prescriptions, over-the-counter meds and dietary supplements made and sold in the U.S. The USP is a not-for-profit independent public health organization. It conducts verification programs for dietary supplement ingredients and products involving independent testing and review. A product is awarded the “USP verification” label only after being shown to:

- Contain ingredients in the amounts stated on the label.
- Be free of harmful levels of contaminants.
- Contain ingredients that will release & dissolve so as to be absorbable in the body.
- Manufactured according to GMP.

Clinical Laboratories (**CL**), an independent quality control agency, also provides a quality seal that can be found on certain products. When looking at a dietary supplement, look for the USP Verified or Clinical Laboratories Approved symbol.



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Our Mission: To identify the best quality health and nutritional products through independent testing.



Do You Need A Dietary Supplement?

80% of Americans are cited as believing that they don't receive adequate levels of needed vitamins and minerals from their diets. Typical eating habits often come up short in meeting daily dietary recommendations to facilitate optimal health.

People most often take dietary supplements as:

- Insurance against inadequate nutrient intake
- Prevention or treatment of disease
- A means to increase energy levels or lower the risk of contracting infectious diseases.

Some of us are especially vulnerable to inadequate nutrient intake. This includes the elderly, the chronically ill, vegans, those with gastrointestinal malabsorption, infants, adolescents, pregnant women, alcohol-addicted individuals, and those who have insufficient food intake. The best strategy for obtaining optimal health is still making healthy choices and consuming of a wide variety of foods. There is currently an explosive growth in the understanding of applied nutrition sciences. More is being learned about the optimal forms of nutrients and of the many beneficial components of food.

Keep in mind that dietary supplements can have unwanted effects, especially if taken before surgery or with other supplements or medications. Some supplements are contraindicated with certain health conditions. Keep your physician informed about what supplements you are taking.

Before Purchasing a Dietary Supplement:

- Research the supplement and compare. Refer to this pamphlet's "Additional Reading and Resources".
- Look for reported negative effects as well as recommendations.
- Check the product packaging to see if it is labeled as CL approved and/or USP verified. Unproven health claims can't be made on the packaging itself. Be cautious of claims & testimonies made in supplemental literature. "Quality seals" and "guarantees" don't mean anything if from unidentified sources or without reputable support.
- Check with your pharmacist or health care provider to ensure that there is no known adverse interaction between a supplement you are considering and a medication you are presently taking. They can recommend proper dosage values for your needs, and warn of possible allergic or anticipated side effects. Don't ever assume that a supplement or over-the-counter medication is safe for you.

Which Supplements Seem to Offer the Most Benefit and the Least Risk?

Compounds which have been around and time tested may be a safe, effective and less costly alternative to taking prescription meds. Lemon juice is well known as a mild diuretic; foods high in the amino acid tryptophan may have a calming effect as a natural sleep aide. Soybean products are a popular plant protein source for the diet because of their role in helping to reduce cholesterol & triglyceride levels, reducing heart disease risk, lessening symptoms of hot flashes for many experiencing menopause, and slowing the onset of osteoporosis. There are also nutritional/ dietary supplements which are showing effectiveness with fewer side effects than prescription counterparts in reproducible, well done research studies.

Additional Reading & Resources

- <http://www.consumerlab.com>
- <http://www.supplementwatch.com>
- <http://eatright.org>
- <http://ahrq.gov> (search for dietary supplements)
- <http://dietary-supplements.info.nih.gov/>
- <http://nccam.nih.gov>
- <http://usp.org>
- <http://naturaldatabase.com>

A Guide to Understanding Dietary Supplements by Shawn M. Talbott, PhD; 2003; The Haworth Press.
Includes a Master Chart on Dietary Supplements.

Handbook of Analytical Methods for Dietary Supplements by Frank Jaksch, Mingfu Wang, Mark Roman.
American Pharmacists Association, 2005.

The Handbook of Clinically Tested Herbal Remedies, Volume 1 and 2 by Marilyn Barrett, PhD, Editor.
The Haworth Press, 2004. A detailed resource book of over 160 herbal products that have been clinically tested, including descriptions of the review procedures and evidence of efficacy.

American Dietetic Association: The Health Professional's Guide to Popular Dietary Supplements, 3rd edition by Allison Sarubin Fragakis, MS, RD and Cynthia Thomson, PhD, RD, 2007.

More than 107 popular vitamins, minerals, amino acids, herbals, enzymes and other supplements are covered in this guide. Helps make sense of the claims and facts surrounding the numerous dietary supplements on the market. *J Am Diet Assoc.*, 2005; 102:460-470