

# ISSUE ★ BRIEF

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## DIETARY SUPPLEMENTS

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### ★ OVERVIEW OF DIETARY SUPPLEMENTS ★

#### *What are Dietary Supplements?*

As defined by Congress in the Dietary Supplement Health and Education Act (DSHEA) of 1994, a dietary supplement is a product taken by mouth that contains an ingredient intended to supplement the diet. The “dietary ingredients” in these products can include vitamins, minerals, herbs and other botanicals; amino acids; and substances such as enzymes, organ tissues, glandulars and metabolites. Dietary supplements also can be extracts or concentrates and may be found in many forms, such as tablets, capsules, softgels, gelscaps, liquids and powders. They also can be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or the sole item of a meal or diet. But whatever their form, the DSHEA places dietary supplements in a special category under the general umbrella of foods, not drugs, and requires that every supplement be labeled a dietary supplement.

Dietary supplements are available without a prescription through a number of retail outlets, including grocery stores, drug stores, general merchandise retailers, natural food stores and specialty health and nutrition stores. Many dietary supplements also can be purchased on the Internet.

### Types of Dietary Supplements

There are many different types of dietary supplements, including herbs and botanicals, minerals, vitamins and amino acids, among others.



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Rows of ginseng plants grow under a canopy in Wisconsin.

#### Herbs and Botanicals

Many different herbal and botanical supplements are on the market. They range from ground-up, exotic herbs such as the kava kava root to well-known and widely used supplements such as ginseng and garlic. Herbs and botanicals are supplements that contain extracts or active ingredients from the roots, berries, seeds, stems, leaves, buds or flowers of plants.

Many herbs and botanicals on the market hold reasonable scientific evidence of benefiting health. Examples include cranberry, *Ginkgo biloba*, St. John's wort, garlic, ginseng, grape seed, green tea and echinacea. Despite these beneficial herbs and botanicals, it is a

common misconception that supplements made from plants are safe because they are "natural" or "organic."

An example of a dangerous plant extract is ephedra, also known as ma huang, ephedrin or ephedrine. Ephedra is an extract of the *Ephedra vulgaris* plant and is marketed as a weight control or energy-boosting formula. Ephedra usually is combined with caffeine, which can augment its adverse effects. It has been known to cause raised blood pressure, nerve damage, muscle injury, psychosis, stroke, memory loss and even death. In fact, 16 states have restricted the sale of ephedra products, and the Food and Drug Administration (FDA) issued a ban on them in late 2003.

#### Vitamins

All vitamins are organic substances that must be supplied in the diet. Without vitamins, humans cannot stay alive, as they are needed in every single organ in the body. Normal, healthy children and adults do not need to take vitamin supplements. In fact, taking excess amounts of vitamins can be dangerous; for example, they can cause liver damage. However, people who drink large amounts of alcohol, smoke cigarettes or are exposed to pollution need extra vitamins. Examples of vitamin dietary supplements include folic acid, vitamin A (beta carotene/carotenoids), vitamin B-12 and vitamin C (ascorbic acid).

#### Minerals

Minerals are nonorganic substances found in all body tissues and fluids, such as bones, teeth, brain, liver, muscle, blood and nerve cells. There are 60 minerals found in the body, 22 of which are considered necessary for good health. Minerals cannot be produced by the body and therefore must be consumed in the diet. Examples include iron, potassium and zinc.

#### Amino Acids

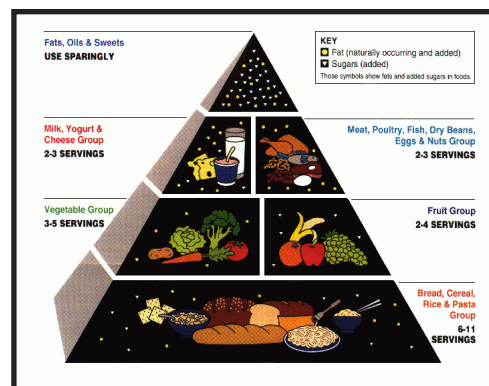
Amino acids are the building blocks of proteins, and approximately three-fourths of the dry weight of every cell in the human body is protein. Proteins are strands of amino acids shaped like necklaces, with the amino acids looking like beads. Proteins differ from one another depending on how the 22 amino acids are combined. Ingested proteins are taken apart into separate amino acids, which then are recombined into the protein chains that create hair, skin, connective tissue, enzymes, hormones, organs and muscle.

Protein is a major component of muscle. For many years, body builders and strength training athletes thought extra protein could increase the rate of muscle building and strength gain. Although some studies have seen increased muscle size result from increased protein intake, few studies have reported an increase in strength.

However, in endurance exercises that last for more than 60 minutes, the body begins to draw on protein and fat stores for fuel. Thus, increased protein consumption from foods or supplements helps replace lost protein and aid in the repair of tissues damaged during exercise. Still, not all amino supplements are safe. Individual amino acid supplements may disrupt the harmonious balance among amino acids in the body.

### Benefits of Dietary Supplements

Today's dietary supplements not only are vitamins and minerals — they also include other, less familiar substances, such as herbals, botanicals, amino acids and enzymes. If you do not consume a variety of foods, as recommended in the *Food Guide Pyramid and Dietary Guidelines for Americans*, some supplements may help ensure that you receive adequate amounts of essential nutrients and help promote optimal health and performance. Scientific evidence supporting the benefits of some dietary supplements (vitamins and minerals, for example) is well-established for certain health conditions.



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In addition, certain segments of the population may benefit from taking dietary supplements. These groups include athletes, older adults, pregnant women, vegetarians and individuals on a weight-loss program. While an adequate and balanced diet is the best way to ensure proper nutrition, these groups may benefit from complementing their diet with a daily multivitamin and mineral supplement.

### Risks of Dietary Supplements

While some dietary supplements are beneficial, there are cases when these products can pose unexpected risks. Many supplements contain active ingredients that can have strong effects on the body. Taking a combination of supplements, using these products together with medicine or substituting them in place of prescribed medicines could lead to harmful and even life-threatening results. Furthermore, some supplements can have unwanted effects before, during and after surgery. It is important to let your doctor and other health professionals know about the vitamins, minerals, botanicals and other products you are taking, especially before surgery.

The following are a few examples of dietary supplements believed to interact with specific drugs:

- Calcium and heart medicine (digoxin, for example), thiazide diuretics and aluminum- and magnesium-containing antacids
- Magnesium and thiazide and loop diuretics (Lasix, for example), some cancer drugs (Cisplatin, for example) and magnesium-containing antacids
- Vitamin K and blood thinners (Coumadin, for example)
- St. John's wort and selective serotonin reuptake inhibitor (SSRI) drugs (Prozac, for example) and birth control pills

It always is a good idea to work with your health care providers before taking a supplement, especially when combining or substituting them with other foods or medicine. Do not try to self-diagnose. Dietary supplements are not intended to treat, diagnose, mitigate, prevent or cure disease, nor are they designed to replace the variety of foods important to a healthful diet.

## ★ RELATED ISSUES

**Regulations**

Drug manufacturers make various claims on dietary supplements' labels. However, manufacturers cannot claim that their product will diagnose, cure, mitigate, treat or prevent a disease. Such claims are illegal for dietary supplements.

Manufacturers may make three types of claims: a health claim, a nutrient content claim or a structure/function claim. Health claims describe a relationship between a dietary supplement ingredient and a reduced risk of a health-related condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance in a product. Structure/function claims describe how a product may affect the organs or systems of the body, but they cannot mention any specific disease. Structure/function claims do not require FDA approval, but the manufacturer must provide the FDA with the text of the claim within 30 days of putting the product on the market. Product labels containing such claims also must include a disclaimer that reads, "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."

The FDA requires that certain information appear on the dietary supplement label. The following general information is required:

- Name of the product (including the word "supplement" or a statement that the product is a supplement)
- Net quantity of contents
- Name and place of business of manufacturer, packer or distributor
- Directions for use

Also required is a supplement facts panel, which lists the serving size, dietary ingredients, amount per serving size (by weight) and percent of daily value, if established. If the dietary ingredient is a botanical, the scientific name of the plant or the common name standardized in the reference *Herbs of Commerce, 2nd Edition* and the name of the plant part used must be listed. If the dietary ingredient is a proprietary blend (a blend exclusive to the manufacturer), the total weight of the blend and the components of the blend in order of predominance by weight must be listed on the panel as well.

Finally, other ingredients must be included on the supplement label, including nondietary ingredients such as fillers, artificial colors, sweeteners, flavors and binders, which must be listed by weight in descending order of predominance and by common name or proprietary blend.

The label of the supplement may contain a cautionary statement, but the lack of a cautionary statement does not mean that no adverse effects are associated with the product.

<b>Supplement Facts</b>	
Serving Size 1 Capsule	
Amount Per Capsule	% Daily Value
Calories 20	
Calories from Fat 20	
Total Fat 2 g	3%*
Saturated Fat 0.5 g	3%*
Polyunsaturated Fat 1 g	†
Monounsaturated Fat 0.5 g	†
Vitamin A 4250 IU	85%
Vitamin D 425 IU	106%
Omega-3 fatty acids 0.5 g	†
* Percent Daily Values are based on a 2,000 calorie diet. † Daily Value not established.	
Ingredients: Cod liver oil, gelatin, water, and glycerin.	

COURTESY FOOD AND DRUG ADMINISTRATION

A sample dietary supplement label.

In the United States, the FDA has regulatory responsibility for dietary supplements. The FDA regulates dietary supplements under a different set of regulations than those covering conventional foods and drug products (prescription and over-the-counter). Under the DSHEA, the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. In addition, manufacturers hold the legal responsibility for ensuring the supplement's product label information is truthful and not misleading.

The FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Unlike drug products that must be proven safe and effective for their intended use before marketing, there are no provisions in the law for the FDA to "approve" dietary supplements for safety or effectiveness before they reach the consumer. Also unlike drug products, manufacturers and distributors of dietary supplements currently are not required by law to record, investigate or forward to the FDA any reports they receive of injuries or illnesses that may be related to the use of their products. Under the DSHEA, once the product is marketed, the FDA has the responsibility for showing that a dietary supplement is "unsafe" before it can take action to restrict the product's use or remove it from the market. The FDA's postmarketing responsibilities include monitoring safety, adverse event reporting and product information, such as labeling, claims, package inserts and accompanying literature.

The Federal Trade Commission (FTC) regulates advertising of dietary supplements in national or regional newspapers and magazines; in radio and television commercials, including infomercials; through direct mail to consumers; and on the Internet. The FTC requires that all information about supplements be truthful and not misleading.

In addition to these regulations, a few independent organizations offer "seals of approval," which may be displayed on certain dietary supplement products. These seals indicate the product has passed the organization's quality tests for things such as potency and contaminants. These seals of approval do not mean the product is safe or effective; they only provide assurance the product was properly manufactured, contains the ingredients listed on the label and does not contain harmful levels of contaminants. Organizations offering these programs include Consumerlab.com, NSF International and U.S. Pharmacopeia.

## ★ EDUCATIONAL ACTIVITY

*Thinking Critically*

The following exercise is intended to stimulate critical thinking about dietary supplements for high school students:

1. Divide the class into four or five smaller groups.
2. Give each group one example of a dietary supplement. Make sure the examples represent the different types of dietary supplements available on the market, including vitamins, minerals, herbs and botanicals and amino acids, among others.
3. Ask each group to research its example dietary supplement and answer the following questions about its supplement:
  - What is the common and brand name for this dietary supplement?
  - What makes this a dietary supplement, and what category of supplements does this example fall under?
  - What are some potential benefits of this supplement?
  - What are some potential risks or adverse effects associated with this supplement?
  - Which groups of the populations likely would see the most benefit, if any, from the use of this dietary supplement?
  - What health claims does the product manufacturer make about the product?
  - What are the main ingredients in the product?
  - Should dietary supplements be more extensively regulated by the federal government?
4. Ask each group to report its findings to the entire class.

## ★ ADDITIONAL RESOURCES

*A Glossary of Terms*

**Absorption:** The digestibility of a dietary supplement into the blood stream.

**Adequate intake:** A dosage recommendation that may be used on a product label where recommended daily dietary allowance information is lacking and that is labeled as daily values.

**Adverse event report:** A report of an incident where it is believed a substance may have caused a health problem or detrimental event.

**Amino acid:** One of the building blocks of protein.

**Antioxidant:** A substance that blocks or inhibits the actions of free radicals, molecules that speed up the aging process and contribute to illness. Free radicals are found in rancid fats and oils and environmental hazards.

**Arteriosclerosis:** A condition in which the walls of arteries become hard and thick, sometimes interfering with blood circulation.

**Bioavailability:** The rate and extent to which a drug or dietary supplement is absorbed into general circulation, thereby permitting access to the site of action. Measured by the concentration in body fluids, usually blood, or by the magnitude of the pharmacological response. Expressed as a fraction of an administered dose.

**Botanical:** A plant-based product.

**Chelation:** A process that wraps or binds the minerals in amino acids. Uses an agent, such as the chemical compound EDTA, to remove heavy metals from the body.

**Clinical trial:** Research studies that use human beings (rather than animals). Clinical trials are conducted in health care settings with voluntary patient-participants.

**Complementary and alternative medicine (CAM):** A group of diverse medical and health care systems, practices and products that currently are not considered to be part of conventional medicine. Complementary medicine is used together with conventional medicine. Alternative medicine is used in place of conventional medicine.

**Dietary reference intakes:** An umbrella term for groups of values that specify recommended dosages.

**Dietary supplement:** Congress defined the term in the Dietary Supplement Health and Education Act of 1994 as “a product taken by mouth that contains a dietary ingredient intended to supplement the diet.”

**Dietary Supplement Health and Education Act (DSHEA):** Passed in 1994, this law amended the Federal Food, Drug, and Cosmetic Act. It created a new regulatory framework for the safety and labeling of dietary supplements, placing them in a special category under the general umbrella of foods and requiring they be labeled as a dietary supplement.

**Disintegration:** The drop in potency of a dietary supplement while in storage as a function of time and storage conditions (light, heat, moisture and air). Stable supplements have a low rate of disintegration, allowing for a later expiration date, while others lose potency comparatively quickly.

**Enzyme:** A complex protein produced by cells that acts as a catalyst in specific biochemical reactions.

**Genetically engineered food:** A food substance that has foreign genes inserted into its genetic code. Genetic engineering can be done with plants, animals or microorganisms. Scientists can move desired genes from one plant into another and even from an animal to a plant, or vice versa.

**Herb:** A plant lacking a permanent, woody stem.

**Holistic medicine:** An approach to medical care that emphasizes the study of all aspects of a person's health, including physical, psychological, social, economic and cultural factors.

**Homeopathy:** A complementary and alternative medical system. In homeopathic medicine, there is a belief that small, highly diluted quantities of medicinal substances are given to cure symptoms, when the same substances given at higher or more concentrated doses actually would cause those symptoms.

**International units:** A term for measurement of vitamins that are fat soluble (do not mix with water and need fat for proper absorption). Vitamins A, E, D and K usually are measured in international units.

**Labeling:** The product label and accompanying material that is used by a manufacturer to promote and market a specific product.

**Microgram:** A metric measurement that is 1/1,000 part of one milligram.

**Milligram:** A metric measurement that is 1/1,000 part of one gram.

**Mineral:** A naturally occurring inorganic substance with a definite and predictable chemical composition and physical properties.

**New dietary ingredient:** A dietary ingredient not sold in the United States in a dietary supplement before Oct. 15, 1994.

**Nutraceutical:** A term coined in the 1990s by Dr. Stephen DeFelice, who defined it as any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease. Such products may range from isolated nutrients, dietary supplements and specific diets to genetically engineered designer foods, herbal products and processed foods such as cereals, soups and beverages. Since the term was coined, however, its meaning has been modified. Health Canada defines it as a product isolated or purified from foods, generally sold in medicinal forms not usually associated with food and demonstrated to have a physiological benefit or provide protection against chronic disease.

**Nutrient:** Any substance that can be metabolized by an organism to give energy and build tissue.

**Potentiated:** 1. To enhance or increase the effect of a drug. 2. To promote or strengthen a biochemical or physiological action or effect.

**Recommended daily dietary allowance:** Started in the 1940s to safeguard the public's health, recommended daily dietary allowances are estimates of the nutritional needs of adults and children. These statistics were developed by the Food and Drug Administration to be used as the legal standards for labeling foods with regard to nutritional content.

**Shelf life:** The period of time during which a dietary supplement remains sufficiently potent to be effective. The expiration date on a product label should indicate the end of this time period.

**Time release:** When a vitamin or mineral has a time-release factor, it means the ingredients have been coated and calibrated scientifically in tiny "memory granules" that are released over a period of two to six hours. The advantage of time release is it gives the body the vitamin or mineral gradually instead of all at once.

**Vitamin:** An organic substance essential in small quantities to normal metabolism.

### *Relevant Links*

<http://ods.od.nih.gov>

The mission of the Office of Dietary Supplements, a unit of the National Institutes of Health, is to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, stimulating and supporting research, disseminating research results and educating the public to foster an enhanced quality of life and health for the U.S. population. This in-depth site includes general information about dietary supplements, information about claims and labeling, training, research programs and funding and links to additional resources.

<http://www.fda.gov>

The Food and Drug Administration is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics and products that emit radiation. Search "dietary supplement" to find several pages dedicated to the topic. These pages include information on the government's regulation process for these products as well as instructions on how to report an adverse event.

<http://fnic.nal.usda.gov>

The Food and Nutrition Information Center (FNIC) is a leader in online global nutrition information. Located at the National Agricultural Library (NAL) of the Department of Agriculture, the FNIC Web site contains more than 2,000 links to current and reliable nutrition information. The center itself was started in 1971 under an agreement between the USDA and the NAL; the mission was to collect and disseminate information about food and human nutrition. The FNIC strives to serve the professional community and consumers by providing access to a wide range of trustworthy food and nutrition resources from both government and nongovernment sources. The site's pages on dietary supplements include general information, safety information and information specific to individual supplements.

<http://www.ftc.gov>

The Federal Trade Commission (FTC) deals with issues that touch the economic lives of most Americans. In fact, the agency has a long tradition of maintaining a competitive marketplace for both consumers and businesses. When the FTC was created in 1914, its purpose was to prevent unfair methods of competition in commerce. Over the years, Congress passed additional laws giving the agency greater authority to police anticompetitive practices. The FTC's Web site contains information on dietary supplement advertising, including how to identify claims and interpret ad meanings.