

What's in the Bottle? An Introduction to Dietary Supplements

Dietary supplements are a topic of great public interest. Whether you are in a store, using the Internet, or talking to people you know, you may hear about supplements and claims of benefits for health. How do you find out whether “what’s in the bottle” is safe to take and whether science has proven that the product does what it claims? This fact sheet provides some answers. To find out more about topics and resources mentioned in this fact sheet, see “For More Information.”

1. What are dietary supplements?

Dietary supplements (also called nutritional supplements, or supplements for short) were defined in a law passed by Congress in 1994 (see the box below).^{1,2}

About Dietary Supplements

A dietary supplement must meet all of the following conditions:

- It is a product (other than tobacco) that is intended to supplement the diet and that contains one or more of the following: vitamins, minerals, herbs* or other botanicals, amino acids, or any combination of the above ingredients.
- It is intended to be taken in tablet, capsule, powder, softgel, gelcap, or liquid form.
- It is not represented for use as a conventional food or as a sole item of a meal or the diet.
- It is labeled as being a dietary supplement.

* Terms that are underlined are defined at the end of this fact sheet.

2. Why do people take supplements?

People take supplements for many reasons. A scientific study on this topic was published in 2002.³ In it, over 2,500 Americans reported on supplements they used (given the categories of vitamins/minerals and herbal products/natural supplements) and for what reasons. Their responses are summarized in the table below.

Supplements: Why Taken?			
Vitamins/Minerals	% of Responses	Herbals/Supplements	% of Responses
Health/good for you	35	Health/good for you	16
Dietary supplement	11	Arthritis	7
Vitamin/mineral supplement	8	Memory improvement	6
Prevent osteoporosis	6	Energy	5
Physician recommended	6	Immune booster	5
Prevent colds/influenza	3	Joint	4
Don't know/no reason specified	3	Supplement diet	4
Immune booster	2	Sleep aid	3
Recommended by friend/family/media	2	Prostate	3
Energy	2	Don't know/no reason specified	2
All others	22	All others	45

3. Is using supplements considered conventional medicine or complementary and alternative medicine (CAM)?

Some uses of dietary supplements have become part of conventional medicine (see box on page 3). For example, scientists have found that the vitamin folic acid prevents certain birth defects, and a regimen of vitamins and zinc can slow the progression of the eye disease age-related macular degeneration.

On the other hand, some supplements are considered to be CAM—either the supplement itself or one or more of its uses. An example of a **CAM supplement** would be an herbal formula that claims to relieve arthritis pain, but has not been proven to do so through scientific studies. An example of a **CAM use of a supplement** would be taking 1,000 milligrams of vitamin C per day to prevent or treat a cold, as the use of large amounts of vitamin C for these purposes has not been proven.

Conventional Medicine

Conventional medicine is medicine as practiced by holders of M.D. (medical doctor) or D.O. (doctor of osteopathy) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses. Other terms for conventional medicine include allopathy; Western, mainstream, orthodox, and regular medicine; and biomedicine.

Complementary and Alternative Medicine (CAM)

CAM is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine. Complementary medicine is used **together with** conventional medicine, and alternative medicine is used **in place of** conventional medicine. Some health care providers practice both CAM and conventional medicine. There is scientific evidence for the effectiveness of some CAM treatments. But for most, there are key questions yet to be answered through well-designed scientific studies, such as whether they are safe and work for the diseases or conditions for which they are used. The National Center for Complementary and Alternative Medicine (NCCAM), part of the National Institutes of Health (NIH), is the Federal Government's lead agency for scientific research on CAM.

4. How can I get science-based information on a supplement?

There are several ways to get information on supplements that is based on the results of rigorous scientific testing, rather than on testimonials and other unscientific information.

- Ask your health care provider. Even if your provider does not happen to know about a particular supplement, he can access the latest medical guidance about its uses and risks.
- Dietitians and pharmacists also have helpful information.
- You can find out if there are any scientific research findings on the CAM supplement in which you are interested. NCCAM and other Federal agencies have free publications, clearinghouses, and databases with this information.

5. If I am interested in using a supplement as CAM, how can I do so most safely?

Here are some points to keep in mind:

- Tell your health care providers about any complementary and alternative practices you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care. It is **especially important** to talk to your provider if you:
 - Are thinking about replacing your regular medical care with one or more supplements.
 - Are taking any medications (whether prescription or over-the-counter). Some supplements have been found to interact with medications (see box on page 4).

- Have a chronic medical condition.
 - Are planning to have surgery. Certain supplements may increase the risk of bleeding or affect anesthetics and painkillers.
 - Are pregnant or nursing a baby.
 - Are considering giving a child a dietary supplement. Supplements can act like drugs, and many have not been tested in pregnant women, nursing mothers, or children.⁴
- Do not take a higher dose of a supplement than what is listed on the label, unless your health care provider advises you to do so.
 - If you experience any side effects that concern you, stop taking the supplement, and contact your provider. You can also report your experience to the U.S. Food and Drug Administration’s (FDA) MedWatch program, which tracks consumer safety reports on supplements.
 - If you are considering or using herbal supplements, there are some special safety issues to consider. See the NCCAM fact sheet “Herbal Supplements: Consider Safety, Too.”
 - For current information from the Federal Government on the safety of particular supplements, check the “Alerts and Advisories” section of the NCCAM Web site or the FDA Web site.

Supplements and Drugs Can Interact

- St. John’s wort can increase the effects of prescription drugs used to treat depression. It can also interfere with drugs used to treat HIV infection, to treat cancer, for birth control, or to prevent the body from rejecting transplanted organs.⁵
- Ginseng can increase the stimulant effects of caffeine (as in coffee, tea, and cola). It can also lower blood sugar levels, creating the possibility of problems when used with diabetes drugs.⁵
- Ginkgo, taken with anticoagulant or antiplatelet drugs, can increase the risk of bleeding. It is also possible that ginkgo might interact with certain psychiatric drugs and with certain drugs that affect blood sugar levels.⁵

6. I see the word “natural” on a lot of supplement labels. Does “natural” always mean “safe”?

There are many supplements, as well as many prescription drugs, that come from natural sources and are both useful and safe. However, “natural” does not always mean “safe” or “without harmful effects.” For example, consider mushrooms that grow in the wild—some are safe to eat, while others are poisonous.

The FDA issues warnings about supplements that pose risks to consumers, including those used for CAM therapies. A sample list is in the box below.^{6,7} The FDA found these products of concern because they:

- Could damage health—in some cases severely.
- Were contaminated—with other unlabeled herbs, pesticides, heavy metals, or prescription drugs.
- Interacted dangerously with prescription drugs.

Examples of Supplements That Have Carried FDA Cautions About Safety	
<ul style="list-style-type: none"> • Ephedra • Kava • Some “dieter’s teas” • L-tryptophan • PC SPES and SPES • Aristolochic acid • Comfrey • St. John’s wort 	<ul style="list-style-type: none"> • GHB (gamma hydroxybutyric acid), GBL (gamma butyrolactone), and BD (1,4-butanediol) • Certain products, marketed for sexual enhancement and claimed to be “natural” versions of the drug Viagra,[®] which were found to contain an unlabeled drug (sildenafil or tadalafil)

7. Does the Federal Government regulate supplements?

Yes, the Federal Government regulates supplements through the FDA. Currently, the FDA regulates supplements as foods rather than drugs. In general, the laws about putting foods (including supplements) on the market and keeping them on the market are less strict than the laws for drugs. Specifically:

- Research studies in people to prove a supplement’s **safety** are not required before the supplement is marketed, unlike for drugs.
- The manufacturer does not have to prove that the supplement is **effective**, unlike for drugs. The manufacturer **can** say that the product addresses a nutrient deficiency, supports health, or reduces the risk of developing a health problem, if that is true. If the manufacturer does make a claim, it must be followed by the statement “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”
- The manufacturer does not have to prove supplement **quality**. Specifically:
 - The FDA does not analyze the content of dietary supplements.
 - At this time, supplement manufacturers must meet the requirements of the FDA’s Good Manufacturing Practices (GMPs) for foods. GMPs describe conditions under which products must be prepared, packed, and stored. Food GMPs do not always cover all

issues of supplement quality. Some manufacturers voluntarily follow the FDA's GMPs for drugs, which are stricter.

- Some manufacturers use the term "standardized" to describe efforts to make their products consistent. However, U.S. law does not define standardization. Therefore, the use of this term (or similar terms such as "verified" or "certified") does not guarantee product quality or consistency.
- If the FDA finds a supplement to be unsafe once it is on the market, only then can it take action against the manufacturer and/or distributor, such as by issuing a warning or requiring the product to be removed from the marketplace.

In March 2003, the FDA published proposed guidelines for supplements that would require manufacturers to avoid contaminating their products with other herbs, pesticides, heavy metals, or prescription drugs. The guidelines would also require supplement labels to be accurate.

The Federal Government also regulates supplement advertising, through the Federal Trade Commission. It requires that all information about supplements be truthful and not mislead consumers.

What's in the Bottle Does Not Always Match What's on the Label

A supplement might:

- Not contain the correct ingredient (plant species). For example, one study that analyzed 59 preparations of echinacea found that about half did not contain the species listed on the label.⁸
- Contain higher or lower amounts of the active ingredient. For example, an NCCAM-funded study of ginseng products found that most contained less than half the amount of ginseng listed on their labels.⁹
- Be contaminated.

8. Is NCCAM supporting research on supplements?

Yes, NCCAM is funding most of the nation's current research aimed at increasing scientific knowledge about supplements—including whether they work; if so, how they work; and how purer and more standardized products could be developed. Among the substances that researchers are studying are:

- Yeast-fermented rice, to see if it can lower cholesterol levels in the blood
- Ginger and turmeric, to see if they can reduce inflammation associated with arthritis and asthma
- Chromium, to better understand its biological effects and impact upon insulin in the body, possibly offering new pathways to treating type 2 diabetes
- Green tea, to find out if it can prevent heart disease

Recent NCCAM-sponsored or cosponsored clinical trials include:

- Glucosamine hydrochloride and chondroitin sulfate, to find out if they relieve knee pain from osteoarthritis
- Black cohosh, to see if it reduces hot flashes and other symptoms of menopause
- Echinacea, to see if it shortens the length or lessens the severity of colds in children
- Garlic, to find out if it can lower moderately high cholesterol levels
- *Ginkgo biloba*, to determine whether it prevents or delays decline in cognitive (thinking) function in people aged 85 or older
- Ginger, to confirm whether it eases nausea and vomiting after cancer chemotherapy

Definitions

Amino acid: Building block of proteins.

Botanical: See “herb.” “Botanical” is a synonym for “herb.”

Clinical trials: Research studies in which a treatment or therapy is tested in people to see whether it is safe and effective.

Depression: An illness that involves the body, mood, and thoughts. The symptoms of depression often include feelings of sadness, hopelessness, or pessimism; and changes in sleep, appetite, and thinking.

Heavy metals: A class of metals that, in chemical terms, have a density at least five times that of water. They are widely used in industry. A few examples of heavy metals that are toxic and have contaminated some dietary supplements are lead, arsenic, and mercury.

Herb: A plant or plant part that is used for its flavor, scent, and/or therapeutic properties.

Testimonials: Information provided by individuals who claim to have been helped or cured by a particular product. The information provided lacks the necessary elements to be evaluated in a rigorous and scientific manner and is not used in the scientific literature.

References

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7. Dietary supplements: warnings and safety information. U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition Web site. Accessed at <http://www.cfsan.fda.gov/~dms/ds-warn.html> on April 14, 2003.
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For More Information

NCCAM Clearinghouse

The NCCAM Clearinghouse provides information on CAM and NCCAM, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners.

Toll-free in the U.S.: 1-888-644-6226

TTY (for deaf and hard-of-hearing callers): 1-866-464-3615

Web site: nccam.nih.gov

E-mail: info@nccam.nih.gov

U.S. Food and Drug Administration (FDA)

The FDA oversees the safety of many products, such as foods (including dietary supplements), medicines, medical devices, and cosmetics.

Web site: www.fda.gov

Toll-free in the U.S.: 1-888-463-6332

Center for Food Safety and Applied Nutrition (CFSAN)

CFSAN oversees the safety and labeling of supplements, foods, and cosmetics.

Publications include “Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information.”

Web site: www.cfsan.fda.gov

Toll-free in the U.S.: 1-888-723-3366

MedWatch

MedWatch, the FDA’s safety information and adverse event reporting program, allows consumers and health care providers to file reports on serious problems suspected with dietary supplements.

Web site: www.fda.gov/medwatch/report/consumer/consumer.htm

Toll-free in the U.S.: 1-888-463-6332

Federal Trade Commission (FTC)

The FTC is the Federal agency charged with protecting the public against unfair and deceptive business practices. A key area of its work is the regulation of advertising (except for prescription drugs and medical devices).

Web site: www.ftc.gov

Toll-free in the U.S.: 1-877-382-4357

Office of Dietary Supplements (ODS), NIH

ODS seeks to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, supporting research, sharing research results, and educating the public. Its resources include publications and the International Bibliographic Information on Dietary Supplements (IBIDS) database.

Web site: www.ods.od.nih.gov

E-mail: ods@nih.gov

PubMed®

A service of the National Library of Medicine (NLM), PubMed contains publication information and (in most cases) brief summaries of articles from scientific and medical journals. CAM on PubMed, developed jointly by NCCAM and NLM, is a subset of the PubMed system and focuses on the topic of CAM.

Web site: www.ncbi.nlm.nih.gov/entrez

CAM on PubMed: nccam.nih.gov/camonpubmed/

The Cochrane Database of Systematic Reviews

The Cochrane Database of Systematic Reviews is a collection of evidence-based reviews produced by the Cochrane Library, an international nonprofit organization. The reviews summarize the results of clinical trials on health care interventions. Summaries are free; full-text reviews are by subscription only.

Web site: www.cochrane.org/reviews

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