

get the facts

Using Dietary Supplements Wisely

Many people take dietary supplements in an effort to be well and stay healthy. With so many dietary supplements available and so many claims made about their health benefits, how can a consumer decide what's safe and effective? This fact sheet provides a general overview of dietary supplements, discusses safety considerations, and suggests sources for additional information.

Key Points

- Federal regulations for dietary supplements are very different from those for prescription and over-the-counter drugs. For example, a dietary supplement manufacturer does not have to prove a product's safety and effectiveness before it is marketed.
- If you are thinking about using a dietary supplement, first get information on it from reliable sources. Keep in mind that dietary supplements may interact with medications or other dietary supplements and may contain ingredients not listed on the label.
- Tell your health care providers about any complementary and alternative practices you use, including dietary supplements. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

About Dietary Supplements

Dietary supplements were defined in a law passed by Congress in 1994 called the Dietary Supplement Health and Education Act (DSHEA). According to DSHEA, a dietary supplement is a product that:

- Is intended to supplement the diet
- Contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and certain other substances) or their constituents
- Is intended to be taken by mouth, in forms such as tablet, capsule, powder, softgel, gelcap, or liquid
- Is labeled as being a dietary supplement.

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary
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NCCAM

Herbal supplements are one type of dietary supplement. An herb is a plant or plant part (such as leaves, flowers, or seeds) that is used for its flavor, scent, and/or therapeutic properties. “Botanical” is often used as a synonym for “herb.” An herbal supplement may contain a single herb or mixtures of herbs.

Research has shown that some uses of dietary supplements are effective in preventing or treating diseases. For example, scientists have found that folic acid (a vitamin) prevents certain birth defects, and a regimen of vitamins and zinc can slow the progression of the age-related eye disease macular degeneration. Also, calcium and vitamin D supplements can be helpful in preventing and treating bone loss and osteoporosis (thinning of bone tissue).

Research has also produced some promising results suggesting that other dietary supplements may be helpful for other health conditions (e.g., omega-3 fatty acids for coronary disease), but in most cases, additional research is needed before firm conclusions can be drawn.

Dietary Supplement Use in the United States

A national survey conducted in 2007 found that 17.7 percent of American adults had used “natural products” (i.e., dietary supplements other than vitamins and minerals) in the past 12 months. The most popular products used by adults for health reasons in the past 30 days were fish oil/omega 3/DHA (37.4%), glucosamine (19.9%), echinacea (19.8%), flaxseed oil or pills (15.9%), and ginseng (14.1%). In another, earlier national survey covering all types of dietary supplements, approximately 52 percent of adult respondents said they had used some type of supplement in the last 30 days; the most commonly reported were multivitamins/multiminerals (35 percent), vitamins E and C (12-13 percent), calcium (10 percent), and B-complex vitamins (5 percent).

Federal Regulation of Dietary Supplements

The Federal Government regulates dietary supplements through the U.S. Food and Drug Administration (FDA). The regulations for dietary supplements are not the same as those for prescription or over-the-counter drugs. In general, the regulations for dietary supplements are less strict.

- A manufacturer does not have to prove the safety and effectiveness of a dietary supplement before it is marketed. A manufacturer is permitted to say that a dietary supplement addresses a nutrient deficiency, supports health, or is linked to a particular body function (e.g., immunity), if there is research to support the claim. Such a claim must be followed by the words “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.”
- Manufacturers are expected to follow certain “good manufacturing practices” (GMPs) to ensure that dietary supplements are processed consistently and meet quality standards. Requirements for GMPs went into effect in 2008 for large manufacturers and are being phased in for small manufacturers through 2010.

- Once a dietary supplement is on the market, the FDA monitors safety. If it finds a product to be unsafe, it can take action against the manufacturer and/or distributor, and may issue a warning or require that the product be removed from the marketplace.

Also, once a dietary supplement is on the market, the FDA monitors product information, such as label claims and package inserts. The Federal Trade Commission (FTC) is responsible for regulating product advertising; it requires that all information be truthful and not misleading.

The Federal Government has taken legal action against a number of dietary supplement promoters or Web sites that promote or sell dietary supplements because they have made false or deceptive statements about their products or because marketed products have proven to be unsafe.

Sources of Science-Based Information

It's important to look for reliable sources of information on dietary supplements so you can evaluate the claims that are made about them. The most reliable information on dietary supplements is based on the results of rigorous scientific testing.

To get reliable information on a particular dietary supplement:

- Ask your health care providers. Even if they do not know about a specific dietary supplement, they may be able to access the latest medical guidance about its uses and risks.
- Look for scientific research findings on the dietary supplement. The National Center for Complementary and Alternative Medicine (NCCAM) and the NIH Office of Dietary Supplements, as well as other Federal agencies, have free publications, clearinghouses, and information on their Web sites.

Safety Considerations

If you are thinking about or are using a dietary supplement, here are some points to keep in mind.

Tell your health care providers about any complementary and alternative practices you use, including dietary supplements. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care. (For tips about talking with your health care providers about CAM, see NCCAM's Time to Talk campaign at nccam.nih.gov/timetotalk/.) It is especially important to talk to your health care provider if you are

- Thinking about replacing your regular medication with one or more dietary supplements.
- Taking any medications (whether prescription or over-the-counter), as some dietary supplements have been found to interact with medications.
- Planning to have surgery. Certain dietary supplements may increase the risk of bleeding or affect the response to anesthesia.

- Pregnant or nursing a baby, or are considering giving a child a dietary supplement. Most dietary supplements have not been tested in pregnant women, nursing mothers, or children.

If you are taking a dietary supplement, **read the label instructions**. Talk to your health care provider if you have any questions, particularly about the best dosage for you to take. If you experience any side effects that concern you, stop taking the dietary supplement, and contact your health care provider. You can also report your experience to the FDA's MedWatch program. Consumer safety reports on dietary supplements are an important source of information for the FDA.

Keep in mind that although many dietary supplements (and some prescription drugs) come from natural sources, **“natural” does not always mean “safe.”** For example, the herbs comfrey and kava can cause serious harm to the liver. Also, a manufacturer's use of the term “standardized” (or “verified” or “certified”) does not necessarily guarantee product quality or consistency.

Be aware that **an herbal supplement may contain dozens of compounds** and that its active ingredients may not be known. Researchers are studying many of these products in an effort to identify active ingredients and understand their effects in the body. Also consider the possibility that what's on the label may not be what's in the bottle. Analyses of dietary supplements sometimes find differences between labeled and actual ingredients. For example:

- An herbal supplement may not contain the correct plant species.
- The amount of the active ingredient may be lower or higher than the label states. That means you may be taking less—or more—of the dietary supplement than you realize.
- The dietary supplement may be contaminated with other herbs, pesticides, or metals, or even adulterated with unlabeled ingredients such as prescription drugs.

For current information from the Federal Government on the safety of particular dietary supplements, check the “Dietary Supplements: Warnings and Safety Information” section of the FDA Web site at www.cfsan.fda.gov/~dms/ds-warn.html or the “Alerts and Advisories” section of the NCCAM Web site at nccam.nih.gov/news/.

Dietary Supplements Research at the National Institutes of Health

NCCAM, which is part of the National Institutes of Health (NIH), is the Federal Government's lead agency for studying all types of CAM. As part of that role, the Center sponsors a wide array of research to see how dietary supplements might affect the body and tests their use in clinical trials. In fiscal year 2007, NCCAM supported more than 200 research projects studying dietary supplements, including herbs and botanicals.

Also within NIH, the Office of Dietary Supplements (ODS) focuses specifically on dietary supplements, seeking to strengthen knowledge by supporting and evaluating research, disseminating results, and educating the public.

NCCAM and ODS collaborate to fund dietary supplement research centers focused on botanicals, known collectively as the NIH Botanical Research Centers Program. Scientists at the centers conduct basic research and other studies on botanicals and help to select products to be tested in clinical trials. The centers are advancing the scientific base of knowledge about botanicals, making it possible to better evaluate their safety and effectiveness.

NCCAM also sponsors a number of Centers of Excellence for Research on CAM, including centers studying antioxidant therapies, botanicals for autoimmune and inflammatory diseases, grape-derived polyphenols for Alzheimer's disease, and botanicals for pancreatic diseases and for colorectal cancer.

Selected References

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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

Office of Dietary Supplements (ODS)

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 (such as *What Dietary Supplements Are You Taking?*), fact sheets on a variety of specific supplement ingredients (such as vitamin D and black cohosh), and the International Bibliographic Information on Dietary Supplements (IBIDS) database.

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

E-mail: ods@nih.gov

U.S. Food and Drug Administration (FDA)

The FDA oversees the safety of many products, such as foods, medicines, dietary supplements, medical devices, and cosmetics. Its series of consumer updates includes the publication *FDA 101: Dietary Supplements* (www.fda.gov/consumer/updates/supplements080408.pdf).

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. Online resources for consumers include “Tips for the Savvy Supplement User: Making Informed Decisions and Evaluating Information” and dietary supplement safety alerts.

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

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/sites/entrez
CAM on PubMed: nccam.nih.gov/research/camonpubmed/

National Library of Medicine's MedlinePlus and Dietary Supplements Labels Database

To provide resources that help answer health questions, MedlinePlus brings together authoritative information from the National Institutes of Health as well as other Government agencies and health-related organizations.

Web site: www.medlineplus.gov

The Dietary Supplements Labels Database provides information about ingredients in more than 2,000 selected brands of dietary supplements, including vitamins, minerals, herbs or other botanicals, amino acids, and other specialty supplements.

Web site: <http://dietarysupplements.nlm.nih.gov/dietary/>

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