

Dietary supplements, including vitamins, minerals, herbs and other botanicals, and amino acids, are used by a growing number of people in the United States. Some of these products have a long history as traditional remedies, especially many herbal and botanical products. Amino acids, enzymes, and some others are fairly new to the marketplace.

mainstream popularity

Dietary supplements have gained mainstream popularity and are sold in major grocery stores, pharmacies, convenience stores, and specialty shops, as well as through direct sales representatives, catalogs, and on the Internet.

a better understanding

This brochure is intended to give you a better understanding of what dietary supplements are, the claims manufacturers can make about the products, and the information listed on the product labels. It also includes a glossary of commonly used terms, a list of questions to ask yourself and your health professional, and a resource section for additional information.

talk to your doctor or pharmacist

If you are currently taking any prescription or over-the-counter (OTC) medicines, you should talk to your doctor or pharmacist before taking these products. Dietary supplements provide consumers with a variety of self-care options; however, it is important to understand that some supplement products have ingredients that may interact with medications and cause potentially serious and unwanted interactions or side effects.

How are dietary supplements regulated?

The Dietary Supplement Health and Education Act of 1994 (DSHEA) is the main law that defines what products are dietary supplements and what types of claims manufacturers can make about the products' health benefits.

Dietary supplements are regulated as a subset of foods, not drugs.

The U.S. Food and Drug Administration (FDA) has jurisdiction over *claims* made on the *product labeling*. Dietary supplements can make claims or statements about the effect of a product on the structure or function of the body. They cannot, however, claim to cure, treat, prevent, mitigate, or diagnose specific diseases, which are drug claims, without FDA authorization.

The U.S. Federal Trade Commission (FTC) has jurisdiction over *advertising* of dietary supplement products, and will take action against false, deceptive, unsubstantiated, or misleading advertising.

Disclaimer

When a structure/function claim, such as "Fiber maintains bowel regularity," is made, the label must provide 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." This statement must appear on all dietary supplement labels that make such claims. What it means is that the FDA has not approved or disapproved the product through scientific testing for treating a specific health condition.

Companies have the responsibility to ensure that products are safe and that the claims made for their products are truthful and

not misleading. Unlike prescription and nonprescription drugs however, dietary supplements do not have to be preapproved for safety or effectiveness by the FDA before they are sold to consumers.

Some labels also include health claims, which describe the relationship of an ingredient to a disease or health condition. An example of such a claim is: "Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life." These claims are authorized by FDA and do not carry a disclaimer.

How to read a dietary supplement label

Know what you are purchasing. Always read the label before you buy or use any dietary supplement product. FDA requires manufacturers to list the following information on the label:

Supplement Facts.

The heading for required information.

Serving size.

How much to take. The amount of each dietary ingredient in each serving—either by percent of daily value (for example, "percent of FDA recommended daily intake from all food sources of vitamin C in each tablet of a multivitamin"), or, if there is no recognized daily value, by weight in each serving (for example, "50 milligrams standardized ginseng extract").

Other ingredients.

10 Questions to ask yourself or your health professional before using any dietary supplement product

1. What is this product for? What is it intended to do?
2. Will this dietary supplement interact with the prescription and OTC medicines I am taking?
3. Are there any side effects? What are they?
4. Are there any precautions or warnings I should know about?
5. How much should I take, when should I take it, and for how long?
6. Are there any foods, drugs, or other supplements I should avoid while taking the product?

Statement of identity.

What the product is (for example, ginkgo biloba).

Name and place of business of manufacturer, packer, or distributor.

In addition to what is required, dietary supplement labels may include additional information, such as:

Warnings and cautions. Who should not take the product, or who should be careful when taking it (for example, pregnant women).

Interactions and side effects.

Any possible reactions that it might have with prescription and OTC medicines, as well as foods or other dietary supplements.

Expiration date. If necessary, the date after which the product should no longer be used.



7. Are there any reasons I should not take this product, such as pregnancy, heart condition, or high blood pressure?

8. Are there any serious symptoms I need to watch out for, such as heart palpitations, dizziness, or night sweats?

9. Where can I get more information about this product or dietary supplements in general?

10. Did I read and understand the label?

Consumer tips

Safety first. Know what you are taking, what it is used for, and how much to take. Dietary supplements may interact with prescription and OTC medicines as well as other supplements and foods. Always read the label and look for warnings, cautions, interactions, or side effects.

Talk to your doctor or pharmacist about all medications and dietary supplements you take.

Never take dietary supplements instead of prescribed medications unless you talk to your doctor.

Remember, dietary supplements are not intended to treat or cure diseases.

Do not believe the hype. If a product sounds too good to be true, it probably is. No product can treat a wide range of unrelated ailments or health conditions. Be wary.

Learn all you can about the products before you take them. See the resource section of this brochure for places to get accurate and unbiased information about dietary supplements.

Natural doesn't always mean safe. Natural products, while not chemically synthesized, may still have the same side effects as similar products produced in a laboratory.

Look for reputable companies. Reputable companies will provide an address and phone number to contact them to receive more product information or answer questions or complaints. If you have any questions or concerns about a product, call or write to the company. If it does not respond, do not use the product.

Glossary of terms

Contraindication. A reason NOT to take a medicine or dietary supplement. Reasons may include pregnancy, unless the dietary supplement is recommended for use in pregnancy, as with, folic acid or folate; an existing health-related condition; or risk of interaction with another medicine, dietary supplement, or conventional food or beverage.

Dietary Ingredient. The specific ingredient in a dietary supplement that provides the effect.

Dietary Supplement. A product that contains one or more dietary ingredients such as vitamins, minerals, herbs or other botanicals, amino acids, or other ingredients used to supplement the diet.

DSHEA. Dietary Supplement Health and Education Act of 1994. The federal law that defines dietary supplements and explains what types of product claims manufacturers can make.

DSHEA Disclaimer. Statement required by the FDA to inform consumers that the FDA has not evaluated a claim being made on the product and to notify consumers that the product is not intended to diagnose, treat, cure, or prevent any disease. This disclaimer must appear on all dietary supplement product labels that make structure/function claims.

FDA. U.S. Food and Drug Administration. The federal agency responsible for oversight and regulation of food, drugs, and cosmetics. Dietary supplements are regulated like a type of food.

FTC. U.S. Federal Trade Commission. The federal agency responsible for regulating the

advertising practices of businesses. The FTC ensures that companies do not provide false or misleading advertising of their products.

Health Claims. Describe the connection between a nutrient or food substance and a disease or health-related condition. FDA must authorize a claim based on a review of scientific evidence or an authoritative statement from certain scientific bodies. An example of a health claim is: "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers."

Interaction. An action between dietary supplements, prescription drugs, OTC medicines, and other medications and/or foods that may change how the supplement or drug is absorbed, metabolized and/or excreted, thereby causing a potentially harmful effect. An interaction also can cause a medication to be less effective because of another medication taken at the same time.

Nutrient Content Claims. These claims describe the level of a nutrient in a food or dietary supplement. For example, a supplement containing at least 200 milligrams of calcium per serving could carry the claim "high in calcium."

OTC Medicines. Over-the-counter medicines are medications that are available without a prescription, such as aspirin and certain cold remedies. These products make drug claims and do not have a DSHEA disclaimer.

Other Ingredients. Ingredients used as additives for color, flavor, binding, or bulk.

Statement of Identity. Describes what the product is, such as ginseng or St. John's wort.

Structure/Function Claims. Statements that describe the role of dietary supplements in supporting wellness (promoting and maintaining health), and refer to the structural part or function of the body they support. Dietary supplement products are allowed to make such claims, provided they are not false or

misleading. Because FDA does not evaluate structure/function claims, they must be accompanied by the disclaimer: "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." An example of these claims is: "Ginseng will help maintain your natural energy." Companies are responsible for ensuring their claims are truthful and not misleading.

Checklist

- ✓ Read the label and follow the directions.
- ✓ Tell your doctor and pharmacist about all medicines and dietary supplements you are currently taking.
- ✓ Know what you are taking and why you are taking it.
- ✓ Do not take more than the recommended amount.



Resources

Food and Drug Administration

Food Information Line: 800-FDA-4010 (800-332-4010),
www.cfsan.fda.gov/~dms/supplmnt.html

FDA MedWatch Program

Report any problems caused by FDA-regulated products such as drugs, medical devices, foods, and dietary supplements to the **MedWatch Hotline**: 800-FDA-1088, (800-332-1088) or www.fda.gov/medwatch/report/bcp.htm
The identity of the caller is kept confidential.

Federal Trade Commission

View brochures, advertising guidelines, and FTC staff comments on dietary supplements at www.ftc.gov/bcp/menu-health.htm, or call 877-FTC-HELP (877-382-4357).

Healthfinder.gov

This Web site provides links to numerous sources of information about health, including dietary supplements. The site is maintained by the United States Department of Health and Human Services at www.healthfinder.gov

National Center for Complementary and Alternative Medicine, National Institutes of Health
www.nccam.nih.gov

NIH Office of Dietary Supplements

301-435-2920, <http://dietary-supplements.info.nih.gov/>

NIH International Bibliographic Information on Dietary Supplements Database

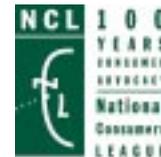
Over 460,000 scientific citations and abstracts of published, international, scientific literature on dietary supplements, including vitamins, minerals, and botanicals are found at <http://ods.od.nih.gov/databases/ibids.html>.

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A Consumer Guide

Dietary Supplements

