

Botanical Dietary Supplements: Background Information

Fact Sheet for Consumers



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What is a botanical?

A botanical is a plant or plant part valued for its medicinal or therapeutic properties, flavor, and/or scent. Herbs are a subset of botanicals. Products made from botanicals that are used to maintain or improve health are sometimes called herbal products, botanical products, or phytomedicines.

In naming botanicals, botanists use a Latin name made up of the plant's genus and a term called the specific epithet. Together, this phrase represents the plant's species name. For example, the botanical black cohosh is known as *Actaea racemosa* L., where "L" stands for Linnaeus, who first described this plant. The Office of Dietary Supplements (ODS) fact sheets do not include such initials because they do not appear on the labels of most products used by consumers.

Can botanicals be classified as dietary supplements?

To be classified as a dietary supplement, a botanical must meet the definition of a dietary supplement as defined by Congress in the Dietary Supplement Health and Education Act of 1994. This act states that a dietary supplement is a product (other than tobacco) that:

- Is intended to supplement the diet
- Contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, or other substances) or their constituents
- Is intended to be taken by mouth as a pill, capsule, tablet, or liquid
- Is labeled as a dietary supplement

How are botanicals commonly sold and prepared?

Botanicals are sold in many forms as both fresh and dried plant materials. For example, a supermarket's produce aisle carries fresh ginger root, while dried ginger root may be found in the dietary supplement aisle in capsule or tablet form, in tea bags, or as a liquid preparation. A group of chemicals or a single chemical may also be isolated from a botanical and sold as a dietary supplement, usually in tablet or capsule form. For example, phytoestrogens from soy products are sold as dietary supplements.

Common ways to prepare botanicals for use include teas, infusions, decoctions, tinctures, and extracts:

- A tea is made by adding boiling water to fresh or dried botanicals and steeping them. An *infusion* is a very strong tea. Teas and infusions may be consumed hot or cold.
- Some roots, bark, and berries require more forceful treatment to extract their desired constituents. They are added to water which is brought to a boil and then simmered at lower heat for several minutes. This also reduces the volume of liquid, producing a more concentrated preparation. Decoctions may be consumed hot or cold.

- A *tincture* is made when a botanical is soaked in a solution of alcohol and water. Tinctures are sold in liquid form and are used for concentrating and preserving a botanical. They are available in different strengths that are expressed as botanical-to-extract ratios (i.e., ratios of the weight of the dried botanical to the volume or weight of the finished product).
- An *extract* is made when the botanical is soaked in a specific liquid, such as water or alcohol, to extract the desired constituents. The extract can be used after the soaking, or it can be evaporated to make a dry extract for use in capsules or tablets.

Are botanical dietary supplements standardized?

Standardization is a process that manufacturers may use for extracts to ensure that all of their batches are similar. The standardization process involves identifying and measuring specific chemicals (also known as markers) and adjusting them to assure consistent amounts in each batch.

Ideally, the chemical markers chosen for standardization would also be the constituents that are responsible for a botanical's effect in the body. If such chemical markers were used, each batch of the product would have the same health effects. However, the constituents responsible for the effects of most botanicals are not known. For example, the sennosides in the botanical senna are responsible for its laxative effect, but many constituents may be responsible for valerian's relaxing effect.

U.S. law does not require dietary supplements to be "standardized." In fact, there is no legal or regulatory definition of the term in the United States.

Are botanical dietary supplements safe?

Some people believe that products labeled "natural" are safe and good for them. This belief is not necessarily correct because the safety of a botanical depends on many things, such as its chemical makeup, how it works in the body, how it is prepared, and the amount used.

The actions of botanicals range from mild to powerful. A botanical with mild action might have subtle effects. Chamomile and peppermint, for example, are usually consumed in teas to help with digestion and are generally considered safe for most people. Some botanicals with mild action might need to be taken for weeks or months before their full effects are achieved. For example, valerian might help users sleep better after a few weeks of use, but just one dose is rarely effective. In contrast, a powerful botanical

produces a fast result. Green tea (a natural source of caffeine) and yohimbe, for example, can have strong and immediate stimulant effects.

The dose and form of a botanical preparation also play important roles in its safety. Teas, tinctures, and extracts have different strengths from one another. For example, the same amount of a botanical may be contained in a cup of tea, a few teaspoons of tincture, or an even smaller amount of an extract. Also, different preparations have different amounts and concentrations of constituents extracted from whole botanicals. For example, peppermint tea is generally considered safe to drink, but peppermint oil is much more concentrated and can be toxic if used incorrectly.

Follow the manufacturer's suggested directions for using a botanical and do not exceed the recommended dose unless your healthcare provider directs otherwise. In fact, you should always talk with your healthcare provider about botanical and other dietary supplements that you are using or are thinking of using.

Does a label indicate the quality of a botanical dietary supplement product?

Determining the quality of a botanical dietary supplement product from its label is difficult. The degree of quality control depends on the manufacturer and others in the production process. The presence of terms such as "standardized", for example, does not necessarily indicate that the product is of high quality.

The U.S. Food and Drug Administration (FDA) has established good manufacturing practices (GMPs) that dietary supplement manufacturers must follow to help ensure the identity, purity, strength, and composition of their dietary supplements. These GMPs can prevent the use of the wrong ingredient (or too much or too little of the right ingredient) and reduce the chance of contamination or improper packaging and labeling of a product. The FDA periodically inspects facilities that manufacture dietary supplements.

Several independent organizations offer quality testing and allow products that pass these tests to display a seal of quality assurance. These seals indicate that a product was properly manufactured, contains the ingredients listed on the label, and does not contain harmful levels of contaminants. However, these seals do not guarantee that a product is safe or effective. Organizations that offer quality testing include:

- ConsumerLab.com
- NSF International
- U.S. Pharmacopeia

What methods are used to evaluate the health benefits and safety of a botanical dietary supplement?

Scientists can use many approaches to evaluate the potential health benefits and risks of botanical dietary supplements. For simple single-ingredient products, they can investigate the history of the botanical's use. They can also conduct laboratory studies of the botanical's effects on cell or tissue cultures, or examine its effects in animals. Studies with people (e.g., individual case reports, observational studies, and clinical trials) provide the most direct evidence of a botanical supplement's effects on health and how people are using it. These studies are important, especially for complex multi-ingredient products.

The amount of scientific evidence available on the health effects and safety of botanical ingredients varies widely. For example, scientists have conducted numerous studies (with mixed results) on the use of black cohosh to treat menopausal symptoms, including hot flashes and night sweats. On the other hand, very little research has been done on some botanical ingredients, such as astragalus, to determine their value.

Through the Consortium for Advancing Research on Botanical and Other Natural Products (CARBON) Program, ODS promotes research on the safety, effectiveness, and mechanisms of action of botanical dietary supplements with high potential to benefit human health. The CARBON program also supports the development of methods and resources to enhance the progress of this research.

Medicines must be evaluated for safety and efficacy and receive FDA approval before they can be sold or marketed, but dietary supplements, including botanicals, do not require FDA approval. The FDA requires supplement companies to have evidence that their products are safe, and claims on product labels must be truthful and not misleading.

What are some additional sources of information on botanical dietary supplements?

- For information about the safety and effectiveness of botanical and other dietary supplement ingredients, see the ODS Dietary Supplement Fact Sheets and the Herbs at a Glance series from the National Center for Complementary and Integrative Health.
- For general information about the use of dietary supplements, see *Dietary Supplements: What You Need to Know*.
- For regulatory information on dietary supplements, visit the FDA website.

Disclaimer

This fact sheet by the Office of Dietary Supplements (ODS) provides information that should not take the place of medical advice. We encourage you to talk to your healthcare providers (doctor, registered dietitian, pharmacist, etc.) about your interest in, questions about, or use of dietary supplements and what may be best for your overall health. Any mention in this publication of a specific product or service, or recommendation from an organization or professional society, does not represent an endorsement by ODS of that product, service, or expert advice.



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