



Botanical Dietary Supplements

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Consumer use of botanical dietary supplements continues to increase throughout the world. In 2002 in the United States, 42 percent of the population reported using one or more botanical dietary supplements.

What are botanicals?

Botanicals are plants or plant parts used for flavor, fragrance, and at times for their medicinal or therapeutic properties. Herbs and spices are two subsets of botanicals. Botanicals are sold either in a crude form (whole dried plants or plant parts as found, for example, in tea bags) or as partially purified or concentrated extracts. These can be liquids or solids in the form of tablets, capsules, softgels, gelcaps, or powders. Sometimes a single chemical or group of chemicals may be isolated from a botanical and sold as a dietary supplement.

When do botanicals become dietary supplements?

To be a dietary supplement, a botanical must meet the following definitions specified in the 1994 Dietary Supplement Health and Education Act (DSHEA).

- Is intended to supplement the diet.
- Contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents.

- Is intended for ingestion in pill, capsule, tablet, or liquid form.
- Is labeled on the front panel as a dietary supplement.
- Is not represented for use as a conventional food or as the sole item of a meal or diet.

What are the top-selling botanicals?

- Ginseng — the wide variety and quality of ginseng used in studies makes it difficult to verify its medicinal benefits, but it has been promoted as a stress-reliever, aphrodisiac, and stimulant.
- St. John's Wort — has a well-proven effect as an antidepressant, but interferes with many drugs.
- Echinacea — became popular in the United States as a natural remedy for infections and inflammation; however there are reports that extended use may result in immune system suppression.
- Ginkgo biloba — has been suggested as a treatment for dementia and as a memory-enhancer, although evidence is inconsistent and unconvincing.
- Garlic — suggested to be a powerful natural antibiotic. Consumption of large amounts in its raw form can irritate or even damage the intestinal tract.

Dietary supplements are big business

More than 158 million Americans regularly consume dietary supplements to maintain and improve their health. In 2000, consumer expenditures on dietary supplements reached a reported \$17 billion, double the amount spent in 1994.

The federal Food and Drug Administration (FDA) predicts that the use of dietary supplements is likely to grow due to:

- Aging of the baby boomer generation.
- Increased interest in self-sufficiency.
- Advances in science that are uncovering new relationships between diet and disease.

What are the advantages of botanical dietary supplements?

- Low cost compared to prescription drugs.
- Available without a prescription.
- Potentially effective, even though the evidence may be lacking.
- Contribute to a sense of self-sufficiency.



St. John's Wort

What are the downsides of botanicals?

- Lack of regulation of small companies can allow for mislabeling plant species used in a product. (A 2007 FDA final rule requires manufacturers to evaluate the identity, purity, quality, strength, and composition of dietary supplements. Companies with more than 20 employees had until June 2009 to comply; companies with fewer than 20 employees have until June 2010 to comply.)

- Lack of clinical evidence to support effectiveness.
- Lack of precise dosing due to inconsistent amounts of ingredients or interaction with drugs, nutrients, or other supplements. To avoid these downsides, purchase botanicals from reputable manufacturers who:
 - Standardize their products.
 - Are committed to quality.
 - Guarantee that pesticides and harmful bacterial contamination are absent.
 - Have carried out research and development to assure a quality product.
 - Offer products manufactured to Good Manufacturing Practices (GMP) standards.



Garlic

How are reputable botanical dietary supplements standardized?

Standardization of a botanical dietary supplement includes:

- Acquiring the botanical from growers or collectors who use good agricultural or collection procedures.
- Authenticating the botanical material to make sure it is the correct species. Some species may contain toxic material.
- Assaying the botanical dietary supplement after processing for hazardous contaminants such as pesticides, herbicides, heavy metals, mycotoxins, and microbes.
- Chemically standardizing the supplement based on the concentration of biologically active compounds.

What is not allowed for a botanical dietary supplement?

- A product sold and promoted on its label and accompanying material by a manufacturer as a botanical dietary supplement that treats, prevents or cures a specific disease or condition would be considered to be an unauthorized new drug by FDA.
- Alteration of a botanical dietary supplement by adding a chemical or substance not listed in the ingredients (sometimes referred to as “fairy dusting”) is never permitted.



Echinacea

What should you do before using a botanical supplement?

- Identify what benefit(s) you expect from the botanical supplement under consideration.
- Purchase the botanical supplement from a reputable source where quality control is guaranteed.
- Consult with your physician before taking any botanical dietary supplement.

Additional sources of information

- Medical libraries
- Web-based resources such as the Food and Drug Administration www.cfsan.fda.gov/~dms/ds-info.html and the National Institutes of Health PubMed www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed.
- For general information about dietary supplements, see Dietary Supplements: Background Information <http://ods.od.nih.gov/factsheets/dietarysupplements.asp> from the Office of Dietary Supplements at the National Institutes of Health.
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