



# Herbal FAQs

## Introduction

The use of herbs and herbal products has become broadly accepted in our contemporary culture. Consumer surveys consistently find that nearly half of all Americans now use herbs, a statistic that is particularly remarkable when we realize that today's herbal products "industry" is just over a quarter century old. In spite of this widespread acceptance of herbal products in individual self-care choices, misconceptions exist as to the regulation, safety and effectiveness of herbal products.

This FAQ (Frequently Asked Questions) format has been developed by the American Herbal Pharmacopoeia and the American Herbal Products Association, two of the leading organizations in the United States for establishing product integrity standards for herbal manufacturers.

## Q. Why should I use herbal products?

The decision to use herbs for their health promoting value is, as with all health decisions, a personal one. There are, however, many good reasons to consider herbal products as complements to your own health care. The best reason, however, may be the fact that herbs and herbal products, with their incredibly wide use throughout time and place, continue to provide real health benefits while maintaining a remarkable safety profile. Readily available natural substances were the first medicines used by humans. Primitive and ancient civilizations as well as contemporary cultures throughout the world have always relied on herbs to provide the benefits that have been observed with their use. In fact, the World Health Organization has estimated that 80 percent of the world's population continues to use traditional therapies, a major part of which are derived from

plants, as their primary health care tools. In our own time and culture, most herbs are available in the form of "herbal supplements." These products are found in the form of teas, tablets, capsules, liquid extracts, and others. We now have ready access to products that bring the herbal traditions from all over the world in a variety of convenient forms. In addition, scientific inquiries continue to develop our knowledge of the benefits of plants, and often validate the observations made over the past centuries.

## Q. Are herbs safe?

Plants that enjoy broad culinary and therapeutic usage are generally safe. We can flavor our food with any number of herbs to make a meal more flavorful. We can appreciate a delicious cup of peppermint leaf or ginger root tea, or benefit from the soothing properties of marshmallow root or the bark of slippery elm. We can take an herbal supplement containing dandelion root or saw palmetto berries, or any number of the other herbs. Although allergies and reactions have been recorded for a few herbs that are widely used in foods and supplements, such individual concerns are also seen with many foods, and do not diminish the safety profile of the many herbs that are generally recognized as safe. On the other hand, and as everyone knows, there are any number of plants that are highly toxic, even deadly. Every ten-year-old hiker knows to stay away from poison ivy (*Toxicodendron* spp.) when walking in the woods. The death sentence imposed on Socrates by an Athenian jury 2,400 years ago was carried out with a fatal dose of poison hemlock (*Conium maculatum*). The poison curare, a blend of several equatorial rain forest plants (e.g., species of *Chondrodendron*, *Curarea* and *Strychnos*) is used by some South American hunter cultures

to make their arrows more deadly. And in the "concrete jungle" of Los Angeles, two young boys died in 2000 from ingesting a few leaves of the ubiquitous oleander (*Nerium oleander*). Federal law — specifically the Federal Food, Drug & Cosmetic Act, and the Dietary Supplement Health and Education Act — and good common sense, however, prevent the use of any such highly toxic plant in products that are readily available to consumers. The better question then, for today's American consumer, is "Are herbal supplement products safe?"

## Q. Are herbal supplement products safe?

Federal law requires that every food product, including herbal supplements, is free of "adulteration" and is not "misbranded." This legal language translates into a requirement that all foods and supplements have a reasonable expectation of safety when offered for sale and when used as directed. So manufacturers of soups, cereals, and supplements all have an obligation to sell only safely made and properly labeled goods, and can find their products subject to seizure should they fail to do so. In addition, manufacturers of herbal products are specifically required to limit their ingredients to either those that were already in the market prior to passage of landmark legislation in 1994 or those that a company can convincingly show, by providing information to the Food and Drug Administration, to be safe. What that means is that any manufacturer who wants to introduce a new herbal ingredient must first provide FDA with information that shows that the herb will be "reasonably expected to be safe." Additionally, the safety of herbal products as a general class has been well established by both their long history of traditional use worldwide and by their broad contemporary use by a significant proportion of the population, estimated



to be nearly half of the U.S. population.

There are so few credible reports of unexpected side effects due to herbal products that most experts consider problems with herbal products to be of only minor or occasional concern. Norman Farnsworth, PhD, Director of the World Health Organization Collaborating Centre for Traditional Medicine and Research Professor of Pharmacognosy at the University of Chicago at Illinois, is generally considered to be one of the most respected experts on the scientific research of botanical medicines. In an article written on the subject of herbal safety, Dr. Farnsworth concluded, "... side effects or toxic reactions associated with herbal medicines in any form are rare. In fact, of all classes of substances reported to cause toxicities of sufficient magnitude to be reported in the United States, plants are the least problematic." This is not to say that every herbal ingredient that is sold as an ingredient in a supplement is appropriate for every consumer or in any quantity. Responsible and informed use by consumers is essential to ensure that herbal products maintain their established safety profile. Accurate product labeling must provide consumers with all information that is material to the use of the product, and such disclosure is required by Federal law.

To assist in assuring that herbal manufacturers provide material information about their products, the American Herbal Products Association (AHPA) has developed specific labeling guidelines for a number of botanical ingredients. Labeling recommendations exist for products containing chaparral (*Larrea tridentata*); comfrey (*Symphytum* spp.); kava (*Piper methysticum*); saw palmetto (*Serenoa repens*); and St. John's wort (*Hypericum perforatum*), among others. In addition, the American Herbal Products Association published an entire volume of information related

to established herbal safety concerns, entitled *Botanical Safety Handbook*. This reference classifies more than 500 herbs with safety categories that can assist both manufacturers in their labeling and consumers in making informed choices in their use of herbs. A general rule for assuring responsible use of an herbal product is to follow all of the labeled directions. If the product bears a caution that suggests that the product is inappropriate for your use, you should take that message seriously. More information can often be provided by an experienced expert, and often from well-informed retail personnel.

#### **Q. Are herbal supplements effective?**

Botanicals have remained a primary source of traditional medicine for millennia. They have made contributions over the last centuries to the development of some of the most widely used and effective modern drugs. In the last several decades, there has been a resurgence of research in the clinical efficacy of herbs. The results of such studies often verify that the empirical observations of the past centuries were accurate. For example, recent studies on the effect of valerian (*Valeriana officinalis*) have produced results that led researchers to conclude that valerian root can produce "significant improvement in sleep quality" and that valerian root extract can be "recommended for the treatment of patients with mild psychophysiological insomnia."

But can a consumer have confidence in the claims made for the products that are available in the market? To begin with, Federal labeling law and regulations for supplements limit allowable claims to those for which a manufacturer "has substantiation that such statement is truthful and not misleading." The manufacturer therefore has a legal burden to assure that the

claim that is made for their products has scientific evidence to back it up. Because there is a greater acceptance of herbal therapies by conventional physicians in Europe, a significant body of clinical data supporting the use of herbs has been developed there. More recently, a number of U.S. companies have designed clinical studies for their branded products. It is estimated that there are over 1,000 clinical trials now being undertaken in the U.S. to increase our knowledge about herbs. The National Institutes of Health has even set up a center with a special focus on "alternative" medicine, and is now concentrating much of its resources on the study of herbal products.

#### **Q. How soon can I expect to notice the benefits of an herbal product?**

Herbs are rich mixtures of diverse natural compounds. Although the effects of certain herbs will be observed within a short time after consumption, others are more subtle and provide their health promoting benefits gradually. If you have ever used ginger root (*Zingiber officinale*) or peppermint leaf (*Mentha x piperita*) tea to promote healthy digestion, you know that you can feel the comforting effects of these herbs almost as you drink the soothing brew. The sense of well-being that results from the use of kava root (*Piper methysticum*) should manifest in only a short time when using a well manufactured product. Similarly, all of the herbs that contain anthrones — such as rhubarb root (*Rheum* spp.) or cascara sagrada bark (*Frangula purshiana*) — will produce a laxative effect within a half a day or so.

Other herbs are known to produce noticeable benefits only after several days or weeks. For example, improvement in sleep when using an extract of valerian root (*Valeriana officinalis*) has been shown to be somewhat dependent



on continued use. With saw palmetto (*Serenoa repens*), the berries of which are used to promote the health of the prostate, the full benefits have been shown in one study to be achieved after 12 to 18 months. Other herbs, such as those that are rich in antioxidants, work to improve your health without a noticeable effect. For more information about what to expect from an herbal product (and when to expect it), consult with the product's manufacturer or an herbal health practitioner. You can find a regional list of herbalists the American Herbalists Guild's professional member referral list at <http://www.americanherbalistsguild.com/>, or your local acupuncturist at the American Association of Oriental Medicine <http://www.aaom.org>.

#### **Q. How do I know how much to use?**

Two different parts of the Federal laws that govern dietary supplements present manufacturers with guidelines for providing quantitative recommendations on the package of their products. First, all supplement manufacturers are responsible for assuring that their products do not present significant or unreasonable risks under conditions of use recommended in labeling or under ordinary conditions of use. In addition, all dietary supplements, including herbal supplements, are required by Federal regulation to identify the "serving size." There are exemptions to the requirement for labeled "Supplement Facts," which includes a statement of serving size, for specifically identified small businesses and for foods in small packages. Exempt manufacturers nevertheless generally provide information about recommended serving. A general recommendation then, with regard to how much of an herbal product to use: the amount recommended on the label. The idea that "more is better" is no more relevant for an herbal supplement than

for any other food that, while it might be delicious, refreshing or nutritive in moderation, becomes unhealthful when consumed in excess. It may also be useful to speak with a qualified herbal expert. A regional list of herbalists is maintained on the American Herbalists Guild's professional member referral list at <http://www.americanherbalistsguild.com/>. Similarly, a local acupuncturist may be found at the American Association of Oriental Medicine at <http://www.aaom.org> and naturopathic physicians can be located through the American Association of Naturopathic Physicians at <http://naturopathic.org>.

#### **Q. How are herbal supplements regulated?**

All supplements, including herbs, vitamins, minerals, etc., must conform to Federal regulations that control their manufacture, labeling, and advertising. In order to sell an herbal supplement, a manufacturer must meet many different Federal (and sometimes state) regulations, and must also adhere to state and local health and business regulations. Since supplements are legally classified as a specifically defined type of food, all supplements are required to be manufactured to the same high standards that are required of all foods. These mandated good manufacturing practice regulations establish basic guidelines to assure that supplements are manufactured under sanitary conditions that result in properly identified products that are not contaminated or adulterated, and that are fit for consumption. Any supplement that does not conform to these basic guidelines is subject to regulatory action by FDA. In addition, all supplement products are required by law to provide certain information about their formulation.

Like foods, supplements must provide consumers with nutritional information.

Unlike foods, supplements must state the quantity of each of the contained ingredients, or of the "proprietary blends" that make up a product. All herbal products are required to identify the parts used of each of the plant ingredients, and to label them with their commonly accepted names. One of the areas of the most detailed Federal regulation of supplements is in the area of product claims, whether on product labels or in advertising. The Food and Drug Administration specifies exactly what kind of claims are allowed, and prohibits the use of any statement that would brand the product as a drug. Herbal supplements are not allowed to make statements regarding prevention, cure, mitigation or treatment of diseases. Instead, their claims are limited to statements that are legally defined as "statements of nutritional support" or "structure/function statements."

Unfortunately, some uninformed writers have published statements that infer that the entire supplement industry is unregulated. Although this unfortunate "fact" has been broadly reported, it is absolutely false. While the details noted above provide some response to this misrepresentation, perhaps the most compelling is that every FDA Commissioner since 1999 has testified before Congress that federal law gives the agency the tools it needs to regulate these products and this industry.

#### **Q. What about interactions with drugs?**

Humans have been learning about the diverse effects of ingesting plants throughout our evolution. We have, by trial and error, found both good and bad effects that are related to specific plants, some of which we use as food, and others that are used for therapeutic purposes. The introduction of synthetic and highly purified drugs is an extremely



modern development. As researchers observe the interactions that drugs have with common foods and herbs, surprises continue to surface. For example, less than 10 years ago it was found that drinking grapefruit juice increases the serum drug concentration when patients take certain drugs. This effect, which can last for up to 24 hours after consumption, is now thought to inhibit specific enzymatic activities responsible for breaking down the drugs. Similarly, both avocado and leafy vegetables that are high in vitamin K can diminish the effectiveness of blood-thinning drugs. These concerns are not widely known by the public, but now that medical professionals are aware of these effects, they can routinely monitor their patients to assure effective treatment.

Similar information has surfaced about some of the herbs that we use. For example, we now know that the use of an extract of St. John's wort (*Hypericum perforatum*) may cause certain prescription medications to be eliminated more quickly, leading one researcher to caution that, as with grapefruit juice, a food product, physicians should also be aware of potential drug-herb interactions. In response to this new information, the American Herbal Products Association has recommended that products containing St. John's wort be labeled to suggest that the advice of your prescribing physician be requested if you are taking any prescription drugs. Speculation on the exact mechanism of St. John's wort has led to reports that the use of this herb might affect oral contraceptives, leading to ineffectiveness and unwanted pregnancies. To date, there have been no reports of any such actual occurrence. Nevertheless, women taking oral contraceptives such as ethinyl estradiol and desogestrel should be aware that, if you experience break-through bleeding, you might experience a reduction in protection against pregnancy.

As can be seen by the above examples, the effect of a drug can be either increased or decreased in the presence of other factors in the diet, including herbal use. Although it is likely that most such factors have little or no influence on drug metabolism, continued research will add to our knowledge of such interactions and responsible food and supplement manufacturers will be expected to inform their customers of any new findings. There is now an ongoing interest in other drugs that are suspected of interacting with certain specific herbs, with most contemporary emphasis on the use of herbs with blood-thinning drugs such as warfarin. Although the current concerns are either conceptual or based on isolated and inconclusive reports, it is advisable to inform your prescribing physician or pharmacist that you are using herbs when undergoing any drug therapy. As close monitoring of the effect of warfarin is an established standard of medical practice, this additional information will assist your physician in maintaining good supervision of your drug levels. In order to understand the potential for an herbal product to interact with prescription drugs, it may also be useful to consult with a qualified herbal expert. You can find a regional list of herbalists the American Herbalists Guild's professional member referral list at <http://www.healthy.net/herbalists>, or your local acupuncturist at the American Association of Oriental Medicine <http://www.aaom.org>. A similar database of naturopathic physicians is maintained by the American Assoc. of Naturopathic Physicians at <http://naturopathic.org>.

**Q. How can I choose the herbal product that is right for me?**

Single herb or combination product? Capsule, tablet, extract or tea? Which brand? Standardized or not? Sometimes it seems that there are just too many choices!! Some of these choices are

ultimately matters of personal choice. The issue of product form is one example — are you attracted to the rich history of herbal extracts and decoctions? ...or do you have trouble swallowing tablets and capsules? Then you may want to try a liquid extract or tea product. On the other hand, if you can't bear the taste of valerian or echinacea, or if you like the convenience of non-liquid forms, you might choose a tablet or capsule. Similarly, there are separate values attached to both single herb products and to herbal formulas. You might appreciate the experience and knowledge that many manufacturers have brought to designing combination products, with a goal toward attaining a higher synergy for the intended use. Multi-ingredient formulas have been the standard in Asian and Indian herbal traditions for centuries. Then again, you might prefer the simplicity of taking only one herb at a time, an approach that has more historical acceptance in the West. Some concern has been stated regarding a conceptual danger in "unknown" herbal combinations. This point of view is apparently uninformed about the historic acceptance of herbal formulas, and is no more relevant to herbal ingredients combined in a supplement product than it would be to the creation of an innovative recipe in your kitchen.

With regard to choosing a brand, one recommendation is to only purchase products from companies who are members of the American Herbal Products Association (AHPA). All AHPA members agree to abide by a Code of Ethics that requires adherence not only to established regulations, but also to meaningful industry policies. Thus, certain business practices that are not mandated by any government agency are expected of all of these companies. One such measure, established as an industry regulation in 1992, called upon all of AHPA's members to agree to a single standardized common name for



each of the herbs used in their products to ensure clear labeling for consumers. This policy was later adopted as Federal law. It is also generally recommended that you buy your herbal product from a reputable company. If the claims made on a particular product are outrageous and unbelievable, especially when compared to other products with the same or similar ingredients, that may be an indication to try another brand. Consider the advice of your retailer, and always feel free to contact the marketer. Those who are selling high quality products will be happy to answer all of your questions and provide you with the assurances that you, their customer, deserve.

Finally, if you have purchased a product that works for you and that provides the promised benefits, stick with it, whether it's a tablet, tincture or tea, whether a single herb or a complex formulation of several herbs. And remember — a brand that is remarkably less expensive than other products with the same or similar ingredients is not always the best bargain.

#### **Q. What are “standardized” herbs?**

The U.S. herbal marketplace has seen the introduction of a number of “standardized” botanical extracts. The purpose of standardization is commonly believed to be control of the content of one or several “marker” compounds, which are perceived of as those constituents in the plant that are responsible for its therapeutic activity. Indeed, there is a common misconception in the U.S. that standardization is equivalent to adding purified compounds to an herb in order to achieve a desired level of the marker compound. In fact, nothing could be further from the truth. The addition of purified compounds in order to achieve

“standardization” actually defeats the purpose of standardization. In fact, standardization — when properly performed — entails a lot more than merely controlling the content of a particular marker compound. Rather, standardization consists of the body of information and manufacturing steps that ensure product consistency from one batch to the next. As such, it comprises a wide variety of raw material and process controls, as well as use of a consistent recipe.

The goal in standardizing an extract is to control the complete chemical composition of the extract, rather than one particular identified constituent or group of constituents. The heightened interest in standardized products is due to the belief that standardization is directly related to the potency of the extract. This is not necessarily the case and can unfortunately lead to a “more is better” perception. It is important to know that the use of marker compounds is not essential to the production of quality botanical products and that many companies market high quality and consistent herbal extracts without reference to these. In addition, any manufacturing process that is too specifically concentrated on maximizing one constituent may place an undue emphasis on that single compound. On the other hand, there can be value in a manufacturing process that implements measures to control the entire spectrum of an herb's constituents and that also includes attention to marker compounds. Consumers should understand that label information about markers is usually provided to communicate product consistency and a degree of quality control rather than potency.

#### **Q. Should I tell my Doctor that I'm using herbs?**

Of course you should! And because your doctor is, ideally, your primary partner in managing your health, you should insist that your doctor, no matter their degree of training in herbs, receive that information respectfully. In telling your doctor of your decision to use an herbal product, however, don't be surprised if you find that your knowledge of herbs is more advanced than theirs. You might suggest (again, respectfully) that they expand their education by using some of the internet resources listed below, or by purchasing and studying some of the written references identified there. At the same time, remember that your prescribing physician has a responsibility to safely oversee your use of any prescription drugs. If your doctor is concerned that a pharmaceutical substance might interact with an herbal product, it is prudent to accept such advice.