



## Herbal Weight-Loss Products: Effective and Appropriate?

BY LESLIE K. KAY, MS, RD

Approximately 60% of American adults are overweight; roughly 30% are technically obese. Americans spend billions on weight-management products, many of which contain herbs formulated to act as stimulants, appetite suppressants, tonics, diuretics, laxatives, and bulking agents.

Generally speaking, weight-loss herbal medicine has a spotty reputation. Ma-huang, an herb used in China for centuries, was reformulated and marketed as a weight-loss product—and the reformulated version has been blamed for severe adverse reactions (even deaths). Another herb, Germander (*Teucrium spp.*), used in England and France, caused liver inflammation, sometimes within a few weeks. Stephania (derived from *Aristolochia fangji*) and magnolia bark were included in a complex weight-loss product and subse-

quently blamed for nearly 100 cases of rapid-onset renal failure in Belgium.

Nevertheless, the use of herbal weight-loss products has increased. Weight-loss supplements accounted for approximately \$1.8 billion in retail sales in 2001 (of a \$17.7 billion supplement market).

Dietitians need to know: Are these products safe and effective?

Many herbs in weight-loss products have a long tradition of use for a variety of ailments. One of the major differences between traditional and modern applications is how the herb is formulated and processed. In traditional medicine, a medicinal herb is a “crude drug” (dried leaves or root, usually) and typically is used as a strong tea (infusion), decoction (simmered in water), or tincture (blended with a solvent such as alcohol, glycerol, or vinegar). Typically, the amount of active ingredient

is small. Modern standardization methods and extraction techniques, however, produce compounds with much higher concentrations than what is normally found in traditional crude drugs.

Herbal extracts (solid, liquid, or powdered) are more potent than tinctures or teas. A solid extract uses four or more parts of botanical material to yield one part of an extract (identified on product labels as higher ratios of plant to solvent (eg, 4:1). Specially concentrated extracts—“standardized extracts”—concentrate active compounds to yield an amount known to have a therapeutic effect. They are most common in compounds designed to suppress appetite.

### APPETITE SUPPRESSANTS

Most conventional pharmacological weight-loss agents are appetite suppressants. The two herbs most often promoted are the tropical fruits *Garcinia cambogia* and *G. indica*. These acidic fruits have a long history of use in India, Laos, Malaysia, Thailand, and Burma for treating abdominal ailments—dysentery, worms, and parasites. The dried rind is used as a condiment; resin extracted from the plant is the medicinal part.

Preliminary laboratory experiments and animal research on hydroxycitric acid (HCA)—up to 16% of the dried fruit—suggest that HCA may potentially aid weight loss. HCA has been shown to significantly reduce food intake (hypothesized by suppressing appetite), body weight gain, and body lipids in rats.<sup>1</sup>

HCA has also been found to inhibit the conversion of carbohydrates into stored fat by inhibiting certain enzymatic pathways. The effects of HCA are based on its action as an inhibitor of the enzyme ATP citrate lyase, which is required for the synthesis of fatty acids. The results of animal studies have yet to be confirmed by well-designed human studies. Clinical trials of *Garcinia* extracts containing 50% HCA (1,000 milligrams to 1,500 milligrams of HCA) daily failed to produce significant weight loss and fat mass loss compared with a placebo. Thus, HCA as a weight-loss aid is questionable. More clinical trials are required before the promotional claims for *Garcinia* and HCA can be substantiated.

### STIMULANTS

In herbal medicine, “stimulant” describes a substance that quickens and enlivens physiological activity. Herbs to stimulate the central nervous system are frequently used in weight-loss aids. Ephedra, guarana, yerba mate, cocoa

extract, bitter orange, citrus arantium, and green tea extract fall into this category.

In general, concentrating any active ingredient that has a stimulatory effect can create problems for people with hypertension, kidney problems, or heart disease. The problem can be further compounded by extraction methods that enhance the concentration of active constituents. (Dietary supplement labels are not required to list extraction techniques or even the degree of potency—only the total number of milligrams of the herb by weight.) The most popular of the stimulants need to be examined individually.

- Ephedra (*Ephedra sinica*, Ma-huang). In Asian medicine, ephedra is the primary herbal drug used for asthma and bronchitis. Ephedra-containing dietary supplements have become increasingly popular to promote weight loss and athletic performance. A recent survey suggests that 7% of the American adult population uses non-prescriptive drugs for weight loss and 1% uses products containing ephedra.<sup>2</sup>

The active ingredients of ephedra are the alkaloids ephedrine and pseudoephedrine, and the effectiveness of this herb is based on isolating these compounds. The traditional dose for Ma-huang recommended in Chinese texts is 1.5 grams to 9 grams per day, with up to 12 grams per day for short-term use. Daily ingestion of ephedrine in traditional teas is 10 milligrams to 80 milligrams. In the United States, promoters of ephedra-containing weight-loss products include 5 milligrams to 75 milligrams of ephedrine alkaloids per serving (for comparison, asthma medications often contain 24 milligrams ephedrine hydrochloride and cold medications contain 60 milligrams to 120 milligrams pseudoephedrine hydrochloride).

Four published studies show clinically significant weight losses when subjects took either 60 milligrams ephedrine/600 milligrams caffeine or 72 milligrams ephedrine/240 milligrams caffeine daily.<sup>3,4</sup> While caffeine can increase the effectiveness of ephedrine, it can also increase unwanted side effects. A meta-analysis of 530 articles, 52 controlled trials, and 65 case studies investigating the efficacy and safety of ephedra for weight loss concluded that ephedrine and ephedra promote modest short-term weight loss (approximately 0.9 kilograms per month more than placebo).<sup>5</sup> No weight-loss trials assessed duration of treatment with ephedra or ephedrine greater than six months. This is minimal effectiveness, considering the possible risks.

Significant adverse effects have been reported to the FDA, some of which resulted in lawsuits and legislation banning ephedra-containing products from at least one state. Several organizations have already banned ephedra (the NCAA, the Olympic

Committee, and the NFL). The adverse effects from ephedrine include insomnia, restlessness, irritability, headaches, nausea, vomiting, and tachycardia. Higher doses (greater than the equivalent of 300 milligrams ephedra alkaloids per day) may produce a drastic increase in blood pressure, cardiac arrhythmia, and development of dependency. Reports of stroke and death have been received by the FDA.

Nevertheless, a comprehensive risk assessment performed by Cantox Sciences International (an independent Canadian research organization) concluded that ephedra is safe under recommended conditions of use, at a total daily dosage of 90 milligrams divided into smaller doses of up to 30 milligrams. The American Herbal Products Association (AHPA) recommends a maximum adult daily dose for ephedra and ephedra-containing products of 100 milligrams total alkaloids.<sup>6</sup>

- Guarana (*Paullinia cupana*) is a concentrated source of caffeine often used in South American soft drinks. It is a metabolic stimulant and diuretic. The active ingredients (from the crushed seeds)

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include tannins, theophylline, theobromine, and caffeine (up to 7%—coffee beans contain 1% to 2% caffeine, and dried tea leaves 1% to 4%).<sup>7</sup>

Guarana is often found in combination with other caffeine-containing herbs (Kola nut) and accentuates the effects of ephedra. One study investigating the effects of a popular non-Western supplement containing guarana (seeds), yerba mate (leaves of *Olea paraguayensis*), and Damiana (leaves of *Turnera diffusa*) demonstrated significant delayed gastric emptying, resulting in significant weight loss, over 45 days in overweight patients.<sup>8</sup> Side effects include nervousness and insomnia. There are few human clinical trials concerning the safety and efficacy of guarana.

- Yerba mate (*Ilex paraguariensis*). “Mate” (*Ilex paraguariensis*, Aquifoliaceae) is a popular tealike beverage consumed mainly in Argentina, Uruguay, Paraguay, and southern Brazil. Brewed from the dried leaves and

stemlets of a perennial tree, it is traditionally used as a tonic and stimulant and in gastrointestinal disorders as a choleric agent (stimulates the release of bile).

The bitter taste properties of mate are attributed to the phenolic constituents (“actives”) of the leaves. Seven South American *Ilex* species contain phenolic compounds and are often used together in traditional mate potions. Decoctions of the leaves induce an increase in bile flow and initiate a mild laxative effect. The therapeutic properties are affected by the presence of other *Ilex* species in the final commercial product of Yerba mate.

Active ingredients are: caffeine (1% to 2%), theobromine (0.45% to 0.9%); theophylline (0.05%); and tanninlike substances (caffeine 4% to 6% and chlorogenic acids, among others).

Mate has been associated as a risk factor for oral and oropharyngeal cancer; however, the populations investigated in many of the studies also used alcohol and tobacco, which may have confounded the herb's influence and are independent risk factors.

The German Commission E was a committee similar to the FDA, assigned by the German government in 1978 to review animal, human clinical studies, and historical use of herbs to create a compendium on the therapeutic benefits and potential risks of herbs and herbal medicine products (phytomedicines). Commission E approved the internal use of mate leaf for mental and physical fatigue. In France, mate leaf preparations are permitted as an adjunct treatment in weight-loss programs and as a diuretic.<sup>9</sup>

- Bitter orange (*Citrus aurantium*), the dried extract of the bitter or Seville (sour) orange fruit (*Citrus aurantium*) (in Chinese medicine: chih-shih or zhishi), is commonly used in Chinese medicine. It contains a compound that acts as a nervous system stimulant and another that acts as a digestive stimulant. The extract differs markedly from the crude herb, a decoction, or any other common preparation used in traditional or folk medicine—the extract may be standardized to contain 6% synephrine and other compounds (octopamine, nordenine, and tyramine).

Traditional use is to stimulate the appetite and for dyspepsia. Commission E approved the cut peel for loss of appetite and dyspeptic ailments. The main constituent in *Citrus aurantium* includes volatile oils, monoterpenes, and flavonoids, among others. However, it also contains synephrine and N-methyltyramine. But, the extract has more of an alkaloid that otherwise appears only in small amounts in Chinese herbal citrus products.

Weight-loss products may contain a 25-fold concentration—a level that can only be attained using extraction methods appropriate to concentrating the alkaloid

## BOTANICALS IN WEIGHT LOSS PRODUCTS

COMMON NAME	USE/CLAIM	EVIDENCE/ EFFICACY	SAFETY	ACTIVE COMPOUNDS
Ephedra	May aid weight loss by suppressing appetite. Thermogenic properties	Significant weight loss in short-term studies	May cause high blood pressure, stroke, and serious heart problems — particularly if used with caffeine	Ephedrine pseudoephedrine
Garcinia cambogia	May interfere with fat metabolism or suppress appetite	equivocal evidence	Generally safe	Hydroxycitric Acid (HCA)
Caffeine	increases fat metabolism/stimulant	potentiates effects of ephedra	Generally safe, caution in caffeine-sensitive individuals	caffeine
green tea extract	promotes thermogenesis, diuretic	limited	same as caffeine	caffeine (up to 7%), catechins, theobromine, epigallocatechin-3-gallate (ECG)
Guarana	Stimulant/diuretic	few clinical trials	same as caffeine	caffeine (2-7%), theobromine (0.7%), tannins
Bitter orange extract (Citrus aurantium)	CNS stimulant	limited evidence	highly concentrated extracts may increase blood pressure, contraindicated in pts. with cardiac problems	synephrine (0.24%), flavonoids
Yerba mate	stimulant, laxative, diuretic	limited evidence	long-term use as a beverage may increase risk of oral cancer	caffeine (1-2%), theobromine, theophylline
senna, cascara, aloe, buckthorn berries	stimulant laxative	not effective for weight loss	chronic use decreases muscle tone in large intestine; electrolyte imbalances and dependence on laxatives	anthraquinones
Tea, Kola, guarana, dandelion, bucho, uva-ursi, damiana, juniper	diuretic	not effective in weight loss	Possible electrolyte imbalance in some patients with chronic use	

fraction. The Seville orange extract *Citrus aurantium* contains m-synephrine (phenylephrine) and octopamine. It causes cardiac disturbances in animals.

Individuals with severe hypertension, tachyarrhythmias, and narrow-angle glaucoma, as well as monoamine oxidase inhibitor recipients, should avoid bitter orange extracts. Persons taking decongestant-containing cold preparations should also refrain. These effects are not reported in the literature for the crude herb, its decoction, or other traditional preparations of citrus materials used in Chinese medicine, but only for the concentrated products.

Interestingly, synephrine occurs in virtually all citrus products. Citrus materials containing synephrine are used in Chinese medicine and have generally been regarded as nontoxic; nonetheless, synephrine and highly concentrated citrus products should not be used for losing weight because the required dosage could produce adverse reactions, especially after prolonged use.

Synephrine is an alkaloid similar in structure to ephedrine and, like many other alkaloids, it stimulates the nervous system. Both ephedrine and synephrine can raise blood pressure and have other effects on cardiac function, which may be beneficial for selected patients when a

proper dosage is administered, but may be harmful for others. Synephrine content ranges from 0.22% to 0.26%.

Citrus products, such as chenpi, zhishi, zhiqiao, and qingpi, are typically prescribed by Chinese physicians in the amount of 3 grams to 9 grams per day—a dosage range similar to Ma-huang. With a synephrine level of approximately 0.25%, and assuming that all is extracted by decoction (as with ephedrine, an 80% yield would be more realistic), a daily dose of the herbs would provide approximately 7.5 mil-

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ligrams to 22.5 milligrams of synephrine, somewhat lower than the amount of ephedrine used in Chinese herb teas.

Specialized, highly concentrated extracts should not be portrayed simply as

herbs. They are unique substances derived from herbs.

- Black and Green Tea (*Camellia sinensis*). The use of tea as a beverage is centuries old. Active ingredients include polyphenols such as gallic acid and catechins, tannins, and caffeine. Xanthine (caffeine, theophylline) derivatives from black tea can diminish the effects of coronary vasodilator drugs and should not be taken concurrently. Liquid teas (infusions) are used as a diuretic in combination with weight-loss products. Side effects include nervousness and insomnia.

Green tea extract is a common ingredient found in weight-loss products and is promoted for its caffeine content and thermogenic properties. Early evidence suggests that green tea extract rich in epigallocatechin-3-gallate can increase calorie and fat metabolism. Green tea extract can contain anywhere from 2% to 20% caffeine by weight. A single tablet of a MetaSlim “weight-loss formula” contains 200 milligrams of green tea (as a powdered extract) concentrated to contain 15% caffeine to provide a total of 30 milligrams of caffeine.

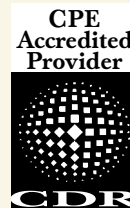
Active ingredients of green tea extract include catechins, polyphenols, and caffeine. The thermogenic effect of tea is generally attributed to its caffeine content. However, the authors of one study conclude that a green tea extract stimulates brown adipose tissue thermogenesis to a much greater extent than can be attributed to its caffeine content alone and that its thermogenic properties could reside primarily in an interaction between its other compounds (catechin-polyphenols) and a synergistic interaction with caffeine.<sup>10</sup>

A clinical trial using a green tea extract (containing 50 milligrams caffeine and 90 milligrams epigallocatechin gallate) in healthy men demonstrated a significant increase in 24-hour energy expenditure compared with a placebo or the same amount of caffeine alone. The authors concluded that green tea extract may play a role in the control of body composition via sympathetic activation of thermogenesis, fat oxidation, or both.<sup>11</sup>

### DIURETICS AND LAXATIVES

Herbal teas marketed as weight-loss products may produce a diuretic and/or laxative effect. This is especially true with herbal teas containing senna, aloe, buckthorn, cascara, and other plant-derived laxatives. Product labels may not directly state that the products are for weight loss and may instead opt for the terms “dieter’s,” “trim,” or “slim” on their product labels. Cascara and senna are available as over-the-counter (OTC) drug laxatives and are regulated as drugs. In excessive amounts, these herbs can cause diarrhea, vomiting, nausea, stomach cramps, and fainting—even death.

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Some herbal products are formulated to contain laxatives as a weight-loss aid. Laxatives containing senna leaves (*Cassia spp.*) or cascara sagrada bark (*Rhamnus purshiana*) have been used for centuries to promote bowel movements and relieve constipation, but are not recommended as part of a weight-loss strategy. Stimulant laxatives that speed the passage of food through the digestive tract are likely to promote dehydration, not fat loss. Long-term use can lead to decreased muscle tone in the large intestine, electrolyte imbalance, and dependence on laxatives.

Herbal diuretics may be divided into two broad groups: those that increase kidney blood flow and those that reduce the water reabsorption in the nephrons of the kidney. Yerba mate (*Ilex paraguariensis*), tea, Kola, and guarana contain up to 2% caffeine, eliciting a small diuretic effect.

Buchu (*Barosma spp.*), Juniper (*Juniperus communis*), uva-ursi (also known as bearberry), damiana (*Turnera diffusa*), and dandelion (*Taraxacum officinale*) also have a diuretic effect and are found to a lesser degree in herbal weight-loss products.

Herbal ingredients formulated for weight loss may actually work in a secondary role that has no direct bearing on weight loss, but play a role in regulating insulin, reducing cravings, and promoting relaxation. Cocoa extract is included in some formulas for its phenylethylamine (PEA). PEA is a neurotransmitter active in stimulation that has been attributed to feelings of affection and love. There is little research to substantiate claims or effectiveness in weight-loss products.

Stimulant herbs such as black pepper, ginger, and cayenne pepper may also be included in formulas to enhance absorption. It has been shown that the compound piperine in long pepper and black pepper increases activity of dietary supplements and conventional pharmaceutical drugs by enhancing the serum concentration, extent of absorption, and bioavailability by inhibiting drug metabolism.<sup>12</sup>

## HERB-DRUG INTERACTIONS

A survey of 3,226 users of Consumerlab.com found that 25% used supplements (herbal and nonherbal combined) for weight management. One of the biggest concerns of health professionals is potential interactions of herbal dietary supplements with prescription and/or OTC drugs. The April-May 1999 *Prevention* magazine survey reported that 18% of patients taking prescription medications were concurrently taking an herbal dietary supplement, which suggests the possibility of herb-drug interactions and raises concerns about safety.

So, how does one determine the safety of botanical ingredients listed on the dietary supplement fact panel? A good way

to start is to refer to the safety rating assigned by the AHPA publication *Botanical Safety Handbook (BSH)*.<sup>13</sup> Classifications are based on data from more than 30 primary references, plus clinical trials, case reports, and other forms of evidence.

The *BSH* was developed as a voluntary form of self-regulation by the herb industry trade group to provide guidelines on the uniform disclosure of potential risk of approximately 550 of the most popular herbs sold in the United States. Table 1 lists the four classifications.

**Table 1**

**Class 1:** Herbs that can be safely consumed when used appropriately

**Class 2:** Herbs for which the following use restrictions apply, unless otherwise directed by an expert, in the use of the described substance:

- 2a: for external use only
- 2b: not to be used during pregnancy
- 2c: not to be used while nursing
- 2d: other specific use restrictions as noted

**Class 3:** Herbs for which significant data exists to recommend the following labeling: "To be used only under the supervision of an expert qualified in the appropriate use of this substance." Labeling must include proper use information: dosage, contraindications, potential adverse effects and drug interactions, and any other relevant information related to the safe use of this substance

**Class 4:** Herbs for which insufficient data is available for classification

## REPORTING SIDE EFFECTS

In May 2003, the FDA's Center for Food Safety and Applied Nutrition (CFSAN) launched a new Adverse Events Reporting System to report and monitor adverse events reports involving foods, cosmetics, and dietary supplements. The new system is called the CFSAN Adverse Events Reporting System (CAERS). Under this program, CFSAN will write a letter of notification to the company listed on the product label when the CAERS system receives an adverse event report of illness or injury allegedly associated with the use of a company's product.

The CAERS system will enable the FDA to identify potential public health issues associated with a particular product already in the marketplace. The FDA will use the information gathered from the system to assist in the formulation and dissemination of CFSAN's postmarketing policies and procedures. The FDA encour-

ages companies to share information with the agency that is relevant and useful concerning adverse events involving their product. This does not have the force of law, however.

The CAERS system replaces the Special Nutritionals/Adverse Event Monitoring System (SN/AEMS) created in 1998. FDA is currently evaluating how best to incorporate the adverse event data received from the CAERS system into a Web site for public use. The SN/AEMS Web site, which included adverse event reports on dietary supplements, has been removed from the FDA Web site. The CAERS system will be pilot-tested this year, however, and may not be placed on the FDA Web site until 2004. In the meantime, the CFSAN internal adverse event collection and evaluation systems will continue to operate.

The American public continues to struggle with the challenge of weight control. The trend toward using dietary supplements as a way to manage weight will likely continue, with herbal products emerging to exploit the demand. Despite their current popularity, there is no herbal magic potion for weight control that is both safe and effective in the long term. More research is necessary to evaluate the safety and efficacy of botanical formulas and their role in weight management. Dietitians should communicate this message to patients struggling with their weight and help them focus on programs that include exercise, behavior modification, and diet. As professionals, we need to monitor and support the FDA's efforts—such as CAERS—to inform and protect our clients.

— Leslie K. Kay, MS, RD, has worked with the dietary supplement industry since 1985; is a speaker on the topics of alternative nutrition, fad diets, and dietary supplements; and is the author of two CE coursebooks: *Herbal Supplements* and *Alternative Nutrition Therapies*. She can be reached at [www.nutritionresource.com/power.htm](http://www.nutritionresource.com/power.htm) or [IHMLeslie@aol.com](mailto:IHMLeslie@aol.com).

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## ADDITIONAL RESOURCES

- The Natural Medicines Comprehensive Database
- The Commission E
- Herbal Medicine Expanded Commission E Monographs
- *The American Botanical Council Clinical Guide to Herbs*
- *Physicians' Desk Reference for Herbal Medicines*
- ADA's Nutrition in Complementary Care Dietetic Practice Group ([www.complementarynutrition.org](http://www.complementarynutrition.org))

## Web site resources include the following:

- National Center for Complementary and Alternative Medicine [www.nccam.nih.gov](http://www.nccam.nih.gov)
- National Institutes of Health Office of Dietary Supplements <http://dietary-supplements.info.nih.gov>
- American Botanical Council [www.herbalgram.org](http://www.herbalgram.org)

## Today's CPE Examination

1. The active ingredient in ephedra is:
  - a. Ephedrine
  - b. Pseudoephedrine
  - c. None of the above
  - d. All of the above
2. Diet supplements may be marketed as:
  - a. Appetite suppressants
  - b. Metabolic stimulants
  - c. Diuretic
  - d. All of the above
  - e. None of the above
3. Which herb contains hydroxycitric acid (HCA) as the active compound?
  - a. Garcinia
  - b. Ephedra
  - c. Yerba mate
  - d. None of the above
  - e. All of the above
4. Caffeine is found in which of the following botanicals?
  - a. Guarana
  - b. Yerba mate
  - c. Green tea
  - d. All of the above
  - e. None of the above
5. Which herbal preparation would contain the highest concentration of active ingredients?
  - a. An infusion
  - b. A decoction
  - c. A solid extract
  - d. None of the above
  - e. All of the above
6. Which of the following botanicals contains synephrine?
  - a. Guarana
  - b. Green tea
  - c. Bitter orange extract
  - d. None of the above
  - e. All of the above
7. Side effects from too much caffeine may include:
  - a. Irritability, headache, insomnia
  - b. Bloating, abdominal distension, gas
  - c. Lowered serum glucose levels
  - d. Weight gain from fluid retention
  - e. None of the above
8. Which of the following botanicals have a laxative effect?
  - a. Cascara
  - b. Senna
  - c. Aloe
  - d. All of the above
  - e. None of the above
9. According to the *American Herbal Products Association's Botanical Safety Handbook*, which classification rates "the herb can be safely consumed when used appropriately"?
  - a. Class 1
  - b. Class 2
  - c. Class 3
  - d. Class 4
  - e. Class 5
10. An herbal dietary supplement labeled as 4:1 ratio indicates that it contains:
  - a. Four parts botanical to one part solvent
  - b. Four parts solvent to one part botanical
  - c. Four units of active ingredient per single serving
  - d. Has been diluted four times to its present strength