

Problems with Weight Loss Products

Nov, 2006 Update:

The publisher of *Pharmacist's Letter* has just made a new arrangement with US Pharmacopeia (USP) to include all the *USP-Verified* Products in *Natural Medicines Comprehensive Database*. This new arrangement allows pharmacists to see all supplement products that have met the quality standards set by USP, and passed USP's verification program.

To see these USP-Verified listings, go to www.naturaldatabase.com.

Good Manufacturing Practices

The FDA requires good manufacturing practices (GMPs) for all drugs. (GMP is sometimes written as "cGMP" for current good manufacturing practices.) Although the FDA has been considering GMP regulations for dietary supplements for a decade, dietary supplement manufacturers are not currently required to follow GMP.^{1,2}

GMPs require accuracy in product labeling. All ingredients, both active and inert, must be detailed on the product label. The quantity of each active ingredient must be listed on the label. GMPs include quality assessment measures to verify label accuracy as well as product purity.^{1,2}

Lack of GMP requirements for dietary supplements has resulted in multiple reports of contaminated products (e.g., heavy metals in traditional Chinese herbal medicines), falsely-labeled products (e.g., product content of ephedra), and incompletely labeled products (e.g., warfarin and other prescription drugs in *PC-SPES*).^{3,4,5}

ConsumerLab.com, an independent testing company, has examined some dietary supplements for weight loss. Of the 23 products tested, nearly half were inaccurately or incompletely labeled.⁶ (Full reports of these tests are available to subscribers of ConsumerLab.com). Here is run-down of the ingredients in the weight-loss supplements and how individual products fared.

Bitter Orange

Bitter orange (*Citrus aurantium*) is a stimulant. It contains synephrine, which is structurally similar to epinephrine, and octopamine, which is similar to norepinephrine. It is widely used by weight-loss supplement manufacturers in "ephedra-free" products to replace ephedra. The FDA removed ephedra from the market because of cardiovascular toxicity.⁷

Limited human research suggests bitter orange, in combination with other ingredients, can cause short-term weight loss.⁷ But, clinical research also suggests bitter orange, particularly in combination with caffeine, can cause increased blood pressure and heart rate – just like ephedra.⁸

Four products were tested for bitter orange content. *Solaray Bitter Orange Extract*, *Thermosculpt*, and *Ripped Fuel* all contained the labeled amount the active constituent of bitter orange, synephrine. A fourth product, *Lean System 7*, was not labeled for its bitter orange content, but contained 55 mg of synephrine.⁶

Caffeine

Caffeine is often included as a constituent of an ingredient called "herbal blend" or "proprietary blend." The FDA does not require labeling of amounts of individual ingredients in herbal blends. Frequently, a total milligram amount is listed for multiple ingredients.^{1,2} Ingredients such as guarana, mate, and kola nut can be significant sources of caffeine, although caffeine *per se* is not listed on the product label.⁷

Several products tested contained large amounts of caffeine. It is useful to relate the caffeine content to that contained in a can of cola, about 40 mg. A daily dose of *Zantrex-3* contained 1223 mg of caffeine (30.6 cans of cola). *Ripped Fuel* contained 581 mg of caffeine (14.5 cans). *Xenadrine-EFX*, which claims that the recommended daily dose contains about as much caffeine as a cup of coffee, contained 448 mg of caffeine (11.2 cans). *TrimSpa X32* contained 173

More . . .

to 346 mg of caffeine, depending on the daily dose used (4.3 to 8.6 cans). *Lean System 7* contained 184 to 276 mg of caffeine, depending on the daily dose used (4.6 to 6.9 cans). *EZ-Trim* contained 180 mg of caffeine (4.5 cans).⁶

Large doses of caffeine can cause headache, anxiety, agitation, ringing in the ears, premature heartbeats, and arrhythmias. Taking caffeine with ephedra increases the risk of serious life-threatening or debilitating adverse effects such as hypertension, myocardial infarction, stroke, seizures, and death.⁷ It is likely that caffeine in combination with bitter orange carries similar risks.⁸

Chromium

Chromium, particularly chromium picolinate, is popularly believed to cause weight loss; however, clinical research has been less optimistic. Chromium might cause about a two-pound weight loss over two to three months.⁷

Trivalent chromium (chromium III) is found in foods and dietary supplements. Hexavalent chromium (chromium VI) is an industrial chemical that is carcinogenic. It can also cause hepatic, renal, and cardiac failure. Chronic use of higher-dose trivalent chromium has also been associated with adverse effects.⁷

ConsumerLab.com set acceptable levels of hexavalent chromium at 0.1%. *TrimSpa X32* contained 0.4% hexavalent chromium, and *Life Extension Chromium 200 mcg Caps* contained 3.8%. Although safe amounts of hexavalent chromium are unknown, avoiding unnecessary exposure is wise.⁶

Labeled amounts of chromium were inaccurate in some products. *TrimSpa X32* contained 42% more than the labeled amount of chromium, yielding a daily dose of 641 mcg. Long-term use of doses exceeding 600 mcg has been linked to hepatic and renal toxicity. *EZ-Trim* contained only 25% of its claimed chromium amount, despite being labeled as “cGMP certified.”⁶

Hydroxycitric Acid

Hydroxycitric acid (HCA) is obtained from garcinia (*Garcinia cambogia*). Although preliminary research suggests it might prevent fat storage and suppress appetite, clinical research to support this is sketchy.⁷

Rainbow Light Garcinia-Max Diet System contained the labeled amount (1,200 mg) of hydroxycitric acid. It also contained 2.6 mcg of lead.⁶ Some botanicals, including garcinia, may naturally contain lead.

7-Keto-DHEA

7-keto-DHEA, known chemically as 3-acetyl-7-oxo-dehydroepiandrosterone, is a dehydroepiandrosterone (DHEA) metabolite. Unlike DHEA, 7-keto-DHEA is not converted to androgens and estrogens. Preliminary research suggests it might increase basal metabolism. One preliminary clinical study suggests 200 mg per day might cause weight loss.⁷

Lean System 7 is labeled with these ingredients: yerba mate, guarana extract, *Citrus aurantium*, 7-keto (3-acetyl-7-oxo-dehydroepiandrosterone), green tea, dandelion, bioperine (piper nigrum). This is listed as a proprietary blend of 693 mg; amounts of individual ingredients are not listed. The maximum suggested daily dose contained 71 mg of 7-keto DHEA.⁶

Pyruvate

Pyruvate is a byproduct of glucose metabolism. Evidence for its use as a weight loss aid is weak. It is also used to enhance exercise capacity and is a common ingredient in body-building products.⁷

Pinnacle Pyruvate 1000 Bioactive Fat Modulator, labeled “1000 mg pyruvate complex,” contained only 600 mg pyruvate. It also seems to have bioavailability problems. Disintegration testing showed it did not fully break apart.⁶

Conjugated Linoleic Acid

Conjugated linoleic acid (CLA) is an isomer of linoleic acid. The primary sources for CLA are dairy products and beef, unlike linoleic acid, which is found in plants. Some research suggests CLA might reduce body fat mass, but it doesn't affect total body weight.⁷

Allmax Nutrition CLA claimed 1,000 mg of CLA per capsule. But it contained only 75% of the labeled amount.⁶

The Bottom Line

Caveat emptor – let the buyer beware – is the byword for advising patients about weight loss

More . . .

supplements. Dietary supplements are not legally bound by good manufacturing practices. Labels may not be accurate. Claims of good manufacturing practices and laboratory testing do not guarantee accuracy or purity. "Bonus ingredients" such as hexavalent chromium may be present.

The FDA removed ephedra from the market after hundreds of reports of serious cardiovascular adverse effects. There is no credible evidence suggesting that bitter orange, particularly when used with caffeine, is any safer than ephedra.⁶

Warn patients about stimulant sources that are not readily apparent on supplement labels. For example, *Lean System 7* contains three sources of caffeine (yerba mate, guarana, and green tea) plus bitter orange (benignly labeled as "*Citrus aurantium*, fruit extract"). A daily dose of *Zantrex-3* contains a whopping 1223 mg of caffeine, but "caffeine" does not appear in the ingredient list.

Some products contain ingredients that might cause adverse effects. The maximum recommended dose of *Zantrex-3* contains 90 mg of niacin, which can cause flushing.⁷

Some products, especially those containing stimulants, can cause short-term weight loss. (Likewise, amputation of an extremity can cause weight loss.) But the risk outweighs the benefit.

Users of this document are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national

organizations. Information and Internet links in this article were current as of the date of publication.

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