

# Congress of the United States

Washington, DC 20515

“...herbal supplements labeled ‘ephedra-free’ are not necessarily safer than ephedra.”

March 8, 2004

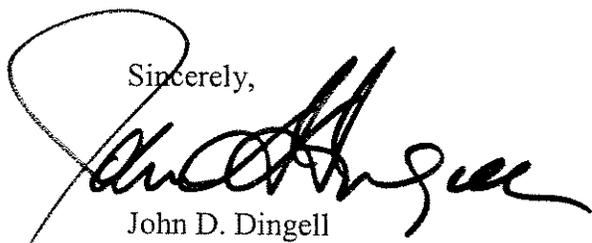
Dear Colleague:

Consumers Union made the statement above in the attached letter. Some in the dietary supplement industry would have us believe that “ephedra-free” weight-loss and energy-boosting supplements are inherently safer than supplements containing ephedra. However, according to a January 2004 Consumer Reports article, some of these ephedra alternatives contain similar central nervous stimulants and may affect the body in ways similar to ephedra. Because dietary supplement manufacturers don’t have to show that their products are safe before marketing, Americans will have no way of knowing the risks of ephedra substitutes until people start getting hurt.

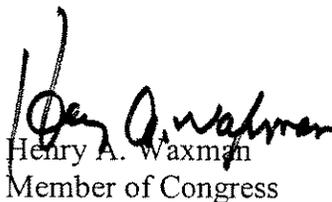
Under current law, supplement manufacturers do not have to demonstrate either that a product is safe or that it works. They don’t even have to tell the FDA that someone has been injured by their products. This makes it very difficult for consumers to know which products work and which products are dangerous. It also makes it impossible for FDA to effectively carry out its mission of making sure that unreasonably dangerous products are not on the market. Please join us in supporting responsible reforms for dietary supplements by co-sponsoring H.R. 3377, the Dietary Supplement Access and Awareness Act. This is common sense legislation that would give consumers greater assurance that their supplements are safe but would not require dietary supplement manufacturers to conduct costly studies to prove that their products are effective. It would not impose any new requirements on supplements containing only vitamins or minerals, such as Vitamin C or calcium products.

If you would like to learn more or become a cosponsor, please contact Patricia Zavala (Rep. Davis) at ext. 5-2040 or Ann Witt (Rep. Waxman) at ext. 5-3976.

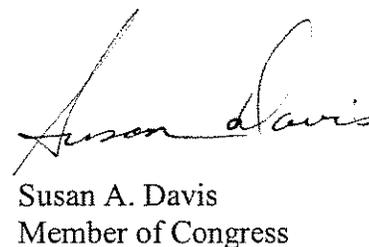
Sincerely,



John D. Dingell  
Member of Congress



Henry A. Waxman  
Member of Congress



Susan A. Davis  
Member of Congress

**Consumers  
Union**

NONPROFIT  
PUBLISHER OF  
CONSUMER REPORTS

February 9, 2004

Dear Representative:

On Friday, the Food and Drug Administration published a final rule banning the sale of dietary supplements containing ephedrine alkaloids ("ephedra" or "ma huang"). Prior to its action banning this ingredient from herbal supplements, the FDA had received at least 16,961 adverse event reports regarding ephedra supplements, including reports of heart attacks, strokes, seizures and fatalities.

We strongly support the FDA's action to ban ephedra. However, we believe that the dangers relating to the use of dietary supplements are not limited to ephedra. Nine years ago, Consumer Reports magazine published a list of five supplements, including ephedra, that the FDA had warned could cause serious harm to consumers. Despite the recent ban on ephedra, the other ingredients highlighted (chaparral, comfrey, lobelia, and yohimbe) continue to be sold today.

In the absence of sufficient FDA action, Consumer Reports continues to strongly urge consumers to avoid all weight-loss and energy-boosting supplements, especially those that are now touted as "ephedra-free." As reported in the January 2004 issue of Consumer Reports (article attached), herbal supplements that are labeled 'ephedra-free' are not necessarily safer than ephedra. Many include similar central nervous stimulants, such as synephrine-containing bitter orange (*citrus aurantium*). Synephrine is not only structurally similar to ephedrine but also may affect the body in ways similar to ephedra. Because there is no required pre-market safety evaluation for those products, consumers have no assurance that the problems experienced by ephedra users will not continue with a switch to ephedra-free products. Of additional concern is the fact that these supplements may interact unfavorably with other medicines that consumers are taking. Unfortunately, not all consumers will receive our message, and may pay with their lives.

In order to prevent additional deaths and serious injuries that can be caused by herbal supplements, we believe that changes must be made to the Dietary Supplement Health and Education Act ("DSHEA"), the law that allows untested dietary supplement products to be widely marketed and sold. We urge you and your colleagues in Congress to make it a priority to provide the FDA with enhanced authority and funding to act quickly when it receives reports regarding unsafe supplements and other untested steroid equivalents. In addition, the federal government should not permit dietary supplements to be sold without adequate pre-market safety testing. Finally, and most important, we believe that dietary supplement manufacturers should be required to submit adverse event information to the FDA, as advocated by Department of Health and Human Services Secretary Tommy Thompson, in a December 30<sup>th</sup> press conference on the ephedra ban. It is only in this way that the FDA can be adequately informed of injuries caused to consumers from the use of a particular product.

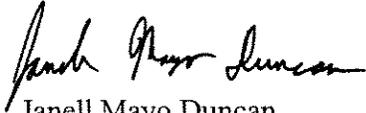
Washington Office

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We urge you to co-sponsor HR 3377, introduced by Representative Susan Davis, which would increase FDA's authority to ensure supplements are safe and require manufacturers to report adverse events.

We look forward to working with you to ensure that consumers can use dietary supplement products safely and with confidence.

Sincerely,



Janell Mayo Duncan  
Legislative and Regulatory Counsel  
Washington Office



Marvin M. Lipman, M.D., FACP  
Chief Medical Adviser  
Yonkers, New York

cc: Tommy G. Thompson, Secretary, Department of Health and Human Services  
Mark B. McClellan, M.D., Ph.D, FDA Commissioner

# EPHEDRA

## HEART DANGERS IN DISGUISE

Despite years of bad publicity, ephedra, a dangerous heart stimulant similar in effect to amphetamines (speed), is still widely available in stores and on the Internet. And it's turning up in products that consumers might not think to check for its presence.

That's what our shoppers found when they visited some 90 stores in seven states and on the Internet to see where they could buy supplements containing ephedra. We also checked product labels for other active ingredients and disclosure of dosages.

By law, labels on dietary supplements must list and give the total quantity of all dietary ingredients. But ephedra, the natural source of the chemical ephedrine, is often listed under other names, such as epitonin, ma huang, sida cordifolia, and sinica. And despite the law, we found at least one product that did not list amounts.

Most of the products we found contain caffeine as well as ephedrine, a combination the government banned in over-the-counter medicines in 1983 because of potential health risks. With some product labels, you need an ingredient dictionary to identify the caffeine; it can appear under names such as guarana, kola nut, maté, paullinia cupana, and tea extracts.

National retail chains, including CVS, Eckerd, GNC, 7-Eleven, and Walgreens, have announced that they no longer stock products with ephedra. So we sent our shoppers to independent pharmacies, gas stations, truck stops, and convenience and health-food stores.

Despite heavy industry lobbying against state and local bans, the manufacture, sale, or distribution of supplements containing ephedra is now illegal in Illinois, New York, and most recently California—home of Metabolife Interna-



tional, one of the largest ephedra supplement makers. Consumers Union, publisher of CONSUMER REPORTS, has lobbied for those laws and for a federal ban on ephedra. Since 1995, we have warned consumers of ephedra's risks.

### Dangerously Unregulated

Since 1993 the Food and Drug Administration has received 16,961 reports of adverse events, including heart attacks, strokes, seizures, and more than 100 deaths associated with ephedra supplements. More than 14,500 of these adverse events were among consumers using the Metabolife 356 weight-loss supplement (records of which the manufacturer withheld from the government for five years).

A report published last March in *Annals of Internal Medicine* showed that products containing ephedra accounted for 64 percent of all adverse reactions to herbal products reported to the American Association of Poison Control Centers in 2001. But the federal government has been slow to act. A federal proposal to require warning labels on all ephedra products was pending at press time.

In light of ephedra's apparent dangers,

the National Football League, the National Collegiate Athletic Association, the International Olympics Committee, and Major League Soccer have banned ephedra's use among players.

But our shoppers found ephedra and ephedra-caffeine combinations not only in weight-loss supplements, the best-known form, but also in supplements marketed as energy boosters or alternatives to street drugs such as ecstasy and speed.

**Energy boosters.** Often sold in small, inexpensive packets near the cash register, these products may have tough-sounding names with teen appeal, such as Midnight Stallion and Black Ice Raging Energizer ("Can you handle it?" challenges the label). The packages' illustrations may have a video-game style. Some products, such as Purple Passion, hint at enhanced sexual stamina as well as energy.

Most products contain combinations of ephedra and caffeine, with many not specifying how much of various ingredients are included. For example, Nitro2Go Explosive Ginseng Energy Formula lists 725 milligrams of a "proprietary blend" of kola nut, ma huang, ginseng, and other herbs. Ultra Energy Now has a whopping 2,805 milligrams for three pills (one serving) of an ephedra-caffeine blend, plus other ingredients like echinacea and kava.

When the caffeine content is specified, the daily dose is often at levels well above what experts consider a moderate daily intake—300 milligrams. If taken as directed, Midnight Stallion and Yellow Swarm Extreme Energizer deliver 900 milligrams of caffeine (equivalent to roughly 6 cups of coffee) a day.

**Fat burners.** Some of the ephedra diet products our shoppers found, such as Twinlab's DietFuel (discontinued but still available in some stores) and Dietcart.com's MetabaLITE, are packaged in fa-

## Ephedra-free But is it safe?

Lawsuits, rising insurance costs, and regulatory uncertainties have encouraged Twinlab Corp., Nature's Bounty, and other supplement manufacturers to reformulate their ephedra products or add ephedra-free options to their existing product lines. Bitter orange and green tea extract are two purportedly safe substitutes.

Like ephedra, both of these ingredients are stimulants. They're often combined with each other and with caffeine, yielding combinations that may pose dangers beyond the sum of their individual effects, says Bill Gurley, Ph.D., professor of pharmaceutical sciences at the University of Arkansas for Medical Sciences and a supplement expert. Further, there's scant evidence that these "new ephedras" can help you lose weight.

Bitter orange (*Citrus aurantium*), also known as green orange or neroli oil, is a featured ingredient in a host of new ephedra-free formulations, including Stacker 2 Ephedra-Free and Twinlab's Diet Fuel Ephedra Free. We even found a bitter-orange product that seemed geared specifically to video-gamers: Mind-FX's Maxx Impulse Terminal Velocity Energy Formula, a blend of green orange and guarana, a form of caffeine.

The active ingredient in bitter orange, synephrine, mimics ephedra in chemical composition and function, constricting the blood vessels and revving up the cardio-

vascular system. There's little evidence that synephrine is effective or safe. Experts suspect that the herb could cause the kinds of problems that ephedra does, such as arrhythmias, anxiety, high blood pressure, heart attack, and stroke, particularly when it's combined with caffeine.

Green tea extract, another ephedra replacement, sounds innocuous; the tea is a healthful source of disease-fighting antioxidants. But in weight-loss and energy supplements, it's generally combined with other caffeine ingredients (as in Metabolife Ephedra Free and Nature's Bounty Super Green Tea Diet) and sometimes with bitter orange (Diet Fuel Ephedra Free).

Green tea itself contains both caffeine and chemicals called catechins, which exacerbate the effects of synephrine, ephedra, and similar compounds. Some preliminary evidence suggests that green tea may help treat obesity. But too much green tea, especially combined with other stimulants, can cause jitters, headaches, insomnia, gastrointestinal upset, and possibly worse problems.

Our medical consultants strongly recommend avoiding all weight-loss and energy-boosting supplements. There are little if any data showing that they work, and there's no convincing evidence that they're safe, even for healthy individuals.



miliar vitamin-type bottles and claim to help you "lose weight" or "enhance your diet." Others, sold in small packets, claim to aid weight loss and increase your energy. For example, our Atlanta shopper bought a packet of JAG Fat Ass-Eliminator, with a roaring-tiger image and four bright-red pills. Dex 975 Fat Burner promises to help "curb appetite," "burn fat and calories," and "maintain energy while dieting." All of these products combine ephedra with caffeine. Some (DietFuel, Stacker 2, and Stacker 3) also lump in other supposed weight-shavers like green tea, L-carnitine (an amino acid), or the mineral chromium picolinate.

**"Legal highs."** Our Internet search quickly turned up multiple sites peddling herbal ecstasy and other street-drug

alternatives made with ephedra and caffeine. A Web site selling 7th Heaven promises "Ephedra in crack-like quantities," "great for intense energy rushes and euphoria." The butterfly-emblazoned label of another product, blue e ecstasy [sic], claims it's a "super energy booster" that will "increase your sense of well being." The 7th Heaven label says it contains 750 milligrams of "Pure Chinese Sinica Extract, Brazilian Guarana, Love and Light," without disclosing the amount of ephedra or caffeine in the pills.

Trip2Night (also sold as T2N and Red Dawn) is advertised as "the best MDMA Ecstasy alternative," as well as an LSD alternative and antidepressant. The T2N label lists ephedra and seven other ingredients, but no amounts—not even total

milligrams per pill. The three sites from which we ordered said we needed to be age 18 or older to purchase, but none requested a date of birth when we entered our order.

In March 2000 the FDA issued guidance to manufacturers that it is illegal to market supplements claiming to mimic street drugs. An FDA representative declined to comment as to whether the products we purchased are being sold illegally, saying the "FDA is taking an aggressive stance on those who violate the law" and that our findings "would be forwarded to compliance officials."

The Federal Trade Commission, which regulates product advertising, took action in 1997 against Global World Media Corp., a company marketing mock street-drug ephedra. Global still sells at least one herbal ecstasy product (7th Heaven), but as a result of a settlement with the FTC, the company now includes a warning on the label stating that the product "may cause an increase in heart rate and blood pressure." No FTC actions on mock street-drug ephedra products have been taken since, an agency representative says.

### WHAT YOU CAN DO

Check labels and avoid products that contain ephedra or ephedra-caffeine combinations, and warn children and teenagers against taking them.

Don't rely on pharmacy or drugstore employees to know which products contain ephedra; one of our shoppers was told by a sales clerk that three products with ma huang didn't contain ephedra.

Keep in mind that with ephedra, as with all supplements, labels may not accurately reflect contents. A University of Arkansas for Medical Sciences analysis of 20 ephedra-containing supplements found that one-quarter had significantly more stimulant content than the labels indicated, and stimulant content often differed markedly among samples of the same product.

Talk to your physician before you take any dietary supplement; some can interfere with the actions of prescription drugs and worsen certain medical conditions.

Report adverse health effects from any dietary supplement to the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch). □