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F.D.A. Finds 'Natural' Diet Pills Spiked With Drugs

By NATASHA SINGER

Grady Jackson, a defensive tackle with the Atlanta Falcons, said he used the weight-loss capsules. [Kathie Lee Gifford](#) was enthusiastic about them on the "Today" show. Retailers like GNC and the Vitamin Shoppe sold them, no prescription required.

But the [Food and Drug Administration](#) now says those weight-loss capsules, called StarCaps and promoted as natural [dietary supplements](#) using papaya, could be hazardous to your health. In violation of the law, the agency has found, the capsules also contained a potent pharmaceutical drug called bumetanide which can have serious side effects.

And StarCaps are not the only culprits. In a continuing investigation that has prompted consumer warnings and recalls by some distributors, the F.D.A. has determined that dozens of weight-loss supplements, most of them imported from China, contain hidden and potentially harmful drugs. In the coming weeks, the agency plans to issue a longer list of brands to avoid that are spiked with drugs, an F.D.A. spokeswoman said.

Besides StarCaps, which were made in Peru and which Balanced Health Products, the American distributor, has voluntarily withdrawn, the agency's warning list includes more obscure pills sold under the names Sliminate, Superslim and Slim Up, among many others. So far, the F.D.A. has cited 69 tainted weight-loss supplements.

"A large percentage of these products either contain dangerous undeclared ingredients or they might be outright fraudulent on the ingredients and have no effect at all," said Michael Levy, the director of the F.D.A.'s division of New Drugs and Labeling Compliance. "We don't think consumers should be using these products."

If a weight-loss supplement does contain an undeclared active pharmaceutical, the F.D.A. considers the product to be an illegal, unapproved drug. Doctors said undeclared drugs could cause problems on their own, like elevated [blood pressure](#) or [seizures](#), could have toxic interactions with other medications people take and could make it difficult for physicians to diagnose patients.

As the F.D.A. continues to investigate, many questions remain to be answered — including who put the drugs in the pills and who knew about it. But some doctors and other experts say the

F.D.A. inquiry raises a larger issue: Whether the regulations governing dietary supplements leave consumers who take so-called natural weight-loss supplements to unknowingly play Russian roulette with their health.

Enacted in 1994, the main law on dietary supplements gives the F.D.A. jurisdiction only after the products go on the market. Rather than reviewing the supplements and approving them for sale, as the agency does with drugs, the F.D.A. is limited to spot-checking manufacturers and distributors, and testing products already on store shelves. Even the F.D.A. acknowledges there may be hundreds of other drug-contaminated weight-loss supplements for sale that the agency does not have the resources to identify.

But even when the agency identifies contaminated products, it does not have the ability to remove the pills from stores, because it is initially up to companies to recall their products. Eventually, though, if contaminated products stay on the market, the F.D.A. can seek injunctions, seize products or file criminal charges.

As of Monday, the American distributors behind only three of the brands named by the F.D.A., including StarCaps, had recalled their tainted pills. Meanwhile, Web sites like 911healthshop.com and fastdietusa.com continue to sell a variety of the other brands, including 3X Slimming Power and Imelda Perfect Slim.

A [full list of the tainted pills and other details](#) are available on the F.D.A.'s Web site, www.fda.gov. An agency spokeswoman said people who want to report problems with the pills could call 1-800-FDA-1088.

"I used to think weight-loss pills were just fancy placebos," said Dr. Pieter Cohen, a general internist at the Cambridge Health Alliance public hospital system in the Boston area. Over the last few years, he said he had treated many patients who took tainted weight-loss pills and came in complaining of chest pains and [heart palpitations](#). "I think doctors need to be a lot more thoughtful — whether patients are buying from local health food stores, off the Internet, or from friends."

A truck driver who is one of Dr. Cohen's patients said he lost 20 pounds by taking what he thought were natural [diet](#) pills imported from Brazil. Unaware that the pills contained high doses of an [amphetamine](#) as well as an antidepressant, the man said he nearly lost his trucking license after he did not pass a drug test at work.

"I failed the drug test and found out the hard way," said the truck driver, 42, who for privacy reasons did not want his name used. His trucking license was suspended for six weeks, but he is now back at work.

Of the nearly \$24 billion spent on dietary supplements in this country in 2007, about \$1.7 billion went for weight-loss pills, according to Nutrition Business Journal, a market research firm. About 15 percent of American adults said they had used weight-loss supplements and the

majority failed to inform their doctors about it, according to a phone questionnaire of 9,500 adults conducted by researchers at the [Centers for Disease Control and Prevention](#) in Atlanta.

Steven M. Mister, the president of the Council for Responsible Nutrition, a trade group whose members include ingredient suppliers and makers of dietary supplements, said that the majority of weight-loss supplements were safe. The F.D.A., he said, is mainly citing obscure imported brands.

But a half-dozen experts interviewed for this article, including government scientists, health activists, doctors and a professor of pharmacy, said that even mainstream natural weight-loss supplements that did not contain hidden drugs could be risky. And they questioned whether such supplements could have any significant effect on weight.

“Whether they have the ability to help people keep the weight off in the long term is unknown,” said Dr. Paul Coates, the director of the Office of Dietary Supplements at the [National Institutes of Health](#) in Washington. He added that even seemingly inert herbs can cause biological changes. “Anything biologically active may turn out to have a risk for somebody.”

Consider ephedra, an herbal stimulant that gained popularity as a weight-loss supplement in the 1990s — until hundreds of people reported ephedra-related problems including heart attacks, seizures and even deaths. The F.D.A. banned the use of ephedra in supplements in 2004.

Last year, the F.D.A. adopted new “good manufacturing practices” rules that require makers of dietary supplements to test the purity of each ingredient and the final product. Another new statute, which went into effect in December 2007, requires manufacturers to notify the F.D.A. of any reports of serious health problems caused by the pills.

“The law adequately protects consumer health because it does have the monitoring system in place,” said Mr. Mister, of the industry trade group.

But Dr. [Sidney M. Wolfe](#), the director of the health research division of the consumer advocacy group [Public Citizen](#), said the regulations did not go far enough. Just because something is uncontaminated does not mean it is safe, he said. For example, Dr. Wolfe said he was concerned about [bitter orange](#), a natural stimulant similar to ephedra that is widely used in weight-loss supplements.

So far no one has taken responsibility for the undeclared drugs in the pills.

StarCaps, the best known of the brands cited, gained a large following through celebrity endorsements and articles in glossy magazines like People. A [billboard](#) featuring the company's founder and proprietor, Nikki Haskell, stood for years above Sunset Boulevard in Hollywood.

After reports surfaced late last fall that StarCaps contained bumetanide, a potent diuretic that was not included on StarCaps' ingredients list, the Vitamin Shoppe and GNC pulled StarCaps

from their shelves, according to e-mail messages from the companies in reply to a reporter's questions. Asked how GNC ensured the safety of such supplements, a spokeswoman wrote, "Like any retailer, we rely on warranties supplied by manufacturers of any third-party product."

Last fall, Mr. Jackson and several other [National Football League](#) players who said they had taken StarCaps failed a drug test when they tested positive for bumetanide. The drug, which can mask [steroid](#) use, is on the list of substances banned by the league.

Now, Mr. Jackson has filed [a class-action suit](#) against Ms. Haskell and the stores where he said he purchased StarCaps, including the Vitamin Shoppe and GNC.

Ms. Haskell said she had been shocked to learn from the news that her product contained the diuretic. Over the last 25 years, she said she had sold several hundred thousand bottles of StarCaps and had never before received a complaint. She voluntarily recalled the products.

"I was completely devastated and remain devastated," Ms. Haskell said.

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