

Beware of Fraudulent 'Dietary Supplements'

Federal regulators continue to warn consumers about tainted, dangerous products that are marketed as dietary supplements. These fraudulent products can cause serious injury or even death.

The Food and Drug Administration (FDA) has found nearly 300 fraudulent products—promoted mainly for weight loss, sexual enhancement, and bodybuilding—that contain hidden or deceptively labeled ingredients, such as

- the active ingredients in FDA-approved drugs or their analogs (closely-related drugs)
- other compounds, such as novel synthetic steroids, that do not qualify as dietary ingredients

“These products are masquerading as dietary supplements—they may look like dietary supplements but they are not legal dietary supplements,” says Michael Levy, director of FDA’s Division of New Drugs and Labeling Compliance. “Some of these products contain hidden prescription ingredients at levels much higher than those found in an approved drug product and are dangerous.”

FDA has received numerous reports of harm associated with the use of these products, including stroke, liver injury, kidney failure, heart palpitations, and death.

Advice for Consumers

“We need consumers to be aware of



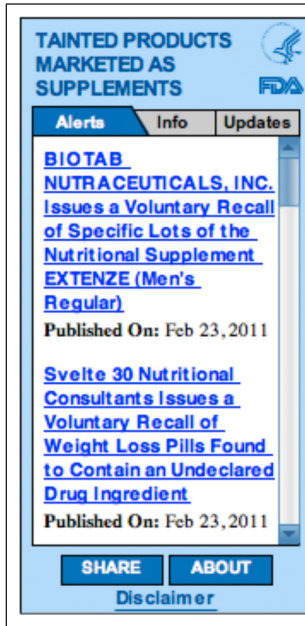
these dangerous products and to learn how to identify and avoid them,” says Levy. Consumers should look for potential warning signs of tainted products marketed as dietary supplements, such as

- products claiming to be alternatives to FDA-approved drugs or to have effects similar to prescription drugs
- products claiming to be a legal alternative to anabolic steroids
- products that are marketed primarily in a foreign language or those that are marketed through mass e-mails
- sexual enhancement products promising rapid effects, such as working in minutes to hours, or long-lasting effects, such as working for 24 to 72 hours
- product labels warning that you may test positive in performance enhancement drug tests

Generally, if you are using or consid-

ering using any product marketed as a dietary supplement, FDA suggests that you

- check with your health care professional or a registered dietician about any nutrients you may need in addition to your regular diet
- ask your health care professional for help distinguishing between reliable and questionable information
- ask yourself if it sounds too good to be true
 - Be cautious if the claims for the product seem exaggerated or unrealistic.
 - Watch out for extreme claims—for example, “quick and effective,” “cure-all,” “can treat or cure diseases,” or “totally safe.”
 - Be skeptical about anecdotal information from personal “testimonials” about incredible benefits or results obtained from using a product.



Keep Up-to-Date on Tainted Products

Get the latest news on tainted products by using FDA's "widget" (www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm242603.htm) and "RSS feed" (www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/TDS/rss.xml). Both of these online tools contain alerts, health information, and FDA actions on tainted products marketed as dietary supplements.

A widget is a portable application that displays featured content directly on a web page. Bloggers or owners of websites can embed this content into their sites. Once FDA's widget is added, there's no technical maintenance—FDA will automatically provide updates to content displayed on the widget.

The RSS (Really Simple Syndication) feed, like the widget, includes updated content published on FDA's website. RSS is usually used for news and blog websites and requires an RSS news reader (a special software program) to pick up the content in the feed. Organizations and bloggers can subscribe to the RSS feed to receive updates automatically and put together their own customized lists of news and information.

° See FDA's website (www.fda.gov/weightlossfraud) to help recognize fraudulent weight-loss products and claims.

If you suspect a dietary supplement sold online may be illegal, FDA urges you to report that information online (www.fda.gov/Safety/ReportAProblem/ucm059315.htm). In addition, you or your health care professional can also report an illness or injury you believe to be related to the use of a dietary supplement by phone at 1-800-FDA-1088 or online (www.fda.gov/Safety/ReportAProblem/ucm053074.htm).

Dietary Supplements and FDA

Dietary supplements, in general, are not FDA-approved. Under the law (Dietary Supplement Health and Education Act of 1994), dietary supplement firms do not need FDA approval prior to marketing their products. It is the company's responsibility to make sure its products are safe and that any claims are true.

Just because you see a supplement product on a store shelf does NOT mean it is safe or effective. When safety issues are suspected, FDA must inves-

tigate and, when warranted, take steps to have the product removed from the market. However, it is much easier for a firm to get a product on the market than it is for FDA to take a product off the market.

FDA has worked with industry to recall numerous products with potentially harmful ingredients including

- more than 40 products marketed for weight loss
- more than 70 products marketed for sexual enhancement
- more than 80 products marketed for body building

FDA last alerted the public to tainted products in December 2010, and will continue to issue consumer alerts and press announcements about these products. The agency has issued warning letters, seized products, and conducted criminal prosecutions. In December 2010, a woman pleaded guilty to an 18-count indictment charging her with the illegal importation and distribution of more than four million diet pills that contained a controlled substance, unapproved drugs, and a possible cancer-causing agent.

Remember, FDA cannot test all prod-

ucts on the market to identify those that contain potentially harmful hidden ingredients. Consumers must also be aware of these dangerous products and learn how to identify and avoid them using the warning signs described above. [FDA](#)

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