



FDA News

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FDA Warns Consumers About Tainted Weight Loss Pills

Agency seeks recall of products that pose serious health risks

The U.S. Food and Drug Administration is alerting consumers nationwide not to purchase or consume more than 25 different products marketed for weight loss because they contain undeclared, active pharmaceutical ingredients that may put consumers' health at risk.

The tainted weight loss products are:

Fatloss Slimming	2 Day Diet	3x Slimming Power
Japan Lingzhi 24 Hours Diet	5x Imelda Perfect Slimming	3 Day Diet
7 Day Herbal Slim	8 Factor Diet	7 Diet Day/Night Formula
999 Fitness Essence	Extrim Plus	GMP
Imelda Perfect Slim	Lida DaiDaihua	Miaozi Slim Capsules
Perfect Slim	Perfect Slim 5x	Phyto Shape
ProSlim Plus	Royal Slimming Formula	Slim 3 in 1
Slim Express 360	Slimtech	Somotrim
Superslim	TripleSlim	Zhen de Shou
Venom Hyperdrive 3.0		

An FDA analysis found that the undeclared active pharmaceutical ingredients in some of these products include sibutramine (a controlled substance), rimonabant (a drug not approved for marketing in the United States), phenytoin (an anti-seizure medication), and phenolphthalein (a solution used in chemical experiments and a suspected cancer causing agent). Some of the amounts of active pharmaceutical

ingredients far exceeded the FDA-recommended levels, putting consumers' health at risk.

These weight loss products, some of which are marketed as "dietary supplements," are promoted and sold on various Web sites and in some retail stores. Some of the products claim to be "natural" or to contain only "herbal" ingredients, but actually contain potentially harmful ingredients not listed on the product labels or in promotional advertisements. These products have not been approved by the FDA, are illegal and may be potentially harmful to unsuspecting consumers.

The FDA advises consumers who have used any of these products to stop taking them and consult their healthcare professional immediately. The FDA encourages consumers to seek guidance from a healthcare professional before purchasing weight loss products.

"These tainted weight loss products pose a great risk to public health because they contain undeclared ingredients and, in some cases, contain prescription drugs in amounts that greatly exceed their maximum recommended dosages," said Janet Woodcock, M.D., director, Center for Drug Evaluation and Research, FDA. "Consumers have no way of knowing that these products contain powerful drugs that could cause serious health consequences. Therefore FDA is taking this action to protect the health of the American public."

The FDA has inspected a number of companies associated with the sale of these illegal products, and is currently seeking product recalls. Based on the FDA's inspections and the companies' inadequate responses to recall requests, the FDA may take additional enforcement steps, such as issuing warning letters or initiating seizures, injunctions, or criminal charges.

The health risks posed by these products can be serious; for example, sibutramine, which was found in many of the products, can cause high blood pressure, seizures, tachycardia, palpitations, heart attack or stroke. This drug can also interact with other medications that patients may be taking and increase their risk of adverse drug events. The safety of sibutramine has also not been established in pregnant and lactating women, or in children younger than 16 years of age.

Rimonabant, another ingredient found in these products, was evaluated, but not approved by the FDA for marketing in the United States. The drug, which is approved in Europe, has been associated with increased risk of depression and suicidal thoughts and has been linked to five deaths and 720 adverse reactions in Europe over the last two years.

Health care professionals and consumers should report serious adverse events (side effects) or product quality problems to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

- Online: www.fda.gov/MedWatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: (800) FDA-0178
- Phone: (800) FDA-1088

Information for consumers can be found at:

http://www.fda.gov/cder/consumerinfo/weight_loss_products.htm

To learn more about FDA's initiative against unapproved drugs read FDA's Compliance Policy Guide here: <http://www.fda.gov/cder/Guidance/6911fnl.htm>.

For drug safety information, read: [FDA's Drug Safety Initiative](#)

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