

FDA Uncovers Additional Tainted Weight Loss Products

Agency alerts consumers to the finding of new undeclared drug ingredients

In 2009, The U.S. Food and Drug Administration expanded, for the second time, its nationwide alert to consumers about tainted weight loss products containing undeclared, active pharmaceutical ingredients.

The FDA has identified additional weight loss products (Herbal Xenicol, Slimbionic, and Xsvelten) and new undeclared active pharmaceutical ingredients (fenproporex, fluoxetine, furosemide, and cetilistat). The current list now includes the following 72 products:

2 Day Diet	Fatloss Slimming	Slim 3 in 1 M18 Royal Diet
2 Day Diet Slim Advance	GMP	Slim 3 in 1 Slim Formula
2x Powerful Slimming	Herbal Xenicol	Slim Burn
3 Day Diet	Imelda Fat Reducer	Slim Express 4 in 1
3 Days Fit	Imelda Perfect Slim	Slim Express 360
3x Slimming Power	JM Fat Reducer	Slim Fast*
5x Imelda Perfect Slimming	Lida DaiDaihua	Slim Tech
7 Day Herbal Slim	Meili	Slim Up
7 Days Diet	Meizitang	Slim Waist Formula
7 Diet	Miaozi MeiMaoQianZiJiaoNang	Slim Waistline
7 Diet Day/Night Formula	Miaozi Slim Capsules	Slimbionic
8 Factor Diet	Natural Model	Sliminate
Eight Factor Diet	Perfect Slim	Slimming Formula
21 Double Slim	Perfect Slim 5x	Somotrim
24 Hours Diet	Perfect Slim Up	Starcaps
999 Fitness Essence	Phyto Shape	Super Fat Burner
BioEmagrecim	Powerful Slim	Superslim
Body Creator	ProSlim Plus	Super Slimming
Body Shaping	Reduce Weighg	Trim 2 Plus
Body Slimming	Royal Slimming Formula	Triple Slim
Cosmo Slim	Sana Plus	Venom Hyperdrive 3.0
Extrim Plus	Slim 3 in 1	Waist Strength Formula
Extrim Plus 24 Hour Reburn	Slim 3 in 1 Extra Slim Formula	Xsvelten
Fasting Diet	Slim 3 in 1 Extra Slim Waist Formula	Zhen de Shou

** This product should not be confused with the line of meal replacement and related products that are marketed as conventional foods under the brand name “Slim-Fast®”. The manufacturer of Slim-Fast®, Unilever United States, Inc., maintains that the Slim Fast product which appears on this list is not in any way associated with, sponsored or approved by, or otherwise related in any way to the Slim-Fast® brand of meal replacement and related 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 maximum recommended dosages,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research. “Consumers have no way of knowing that these products contain dangerous drugs that could cause serious consequences to their health.”

On Dec. 22, 2008, the FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. On Jan. 8, 2009, the FDA expanded the list of tainted weight loss products to include 41 additional tainted products. The FDA will continue to update this list as warranted.

The products listed above, some of which are marketed as dietary supplements, are promoted and sold on various Web sites and in some retail stores and beauty salons. Some of the products claim to be “natural” or to contain only “herbal” ingredients, but actually contain potentially harmful ingredients not listed on the products’ labels or in promotional advertisements.

These products have not been approved by the FDA, are illegal, and include the following undeclared active pharmaceutical ingredients:

- sibutramine (an appetite suppressant available by prescription only and a controlled substance)
- fenproporex – a controlled substance not approved for marketing in the United States;
- fluoxetine – an antidepressant available by prescription only;
- bumetanide – a potent diuretic available by prescription only;
- furosemide – a potent diuretic available by prescription only;
- rimonabant – a drug not approved for marketing in the United States;
- cetilistat – an experimental obesity drug not approved for marketing in the United States;
- phenytoin – an anti-seizure medication available by prescription only; and
- phenolphthalein – a solution used in chemical experiments and a suspected cancer-causing agent that is not approved for marketing in the United States.

The FDA has inspected a number of companies associated with the sale of these illegal products and continue to seek 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 FDA advises consumers who have used any products containing these ingredients to stop taking them and consult their health care professional immediately. The FDA also encourages consumers to seek guidance from a health care professional before purchasing weight loss products.

The health risks posed by these products can be very serious and include high blood pressure, seizures, tachycardia (rapid heartbeat), palpitations, heart attack, and stroke. Sibutramine, a controlled substance, was found in many of these products at levels much higher than the maximum daily dosage for Meridia, the only FDA-approved drug product containing sibutramine. These higher levels of sibutramine can increase the incidence and severity of these health risks. Fenproporex, another controlled substance, can cause arrhythmia and possible sudden death.