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FDA News

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FDA Expands Warning to Consumers About Tainted Weight Loss Pills

List increases from 28 to 69 products; Agency seeking recalls

The U.S. Food and Drug Administration is expanding its nationwide alert to consumers about tainted weight loss pills that contain undeclared, active pharmaceutical ingredients. On December 22, 2008, FDA warned consumers not to purchase or consume 28 different products marketed for weight loss. Since that time, FDA analysis has identified 41 more tainted weight loss products 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	5x Imelda Perfect Slimming	3 Day Diet

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	Starcaps	Slim Waistline
Slim Waist Formula	Slim Up	Sliminate
Slim Fast	2x Powerful Slimming	Slim Express 4 in 1
Reduce Weihgt	Super Fat Burner	Super Slimming
Sana Plus	Trim 2 Plus	Powerful Slim
Waist Strength Formula	Slimming Formula	Perfect Slim Up
Slim Burn	Slim 3 in 1 Slim Formula	Slim 3 in 1 M18 Royal Diet
Slim 3 in 1 Extra Slim Waist Formula	Slim 3 in 1 Extra Slim Formula	Natural Model
2 Day Diet Slim Advance	Miaozi MeiMiaoQianZiJiaoNang	Meizitang
Meili	JM Fat Reducer	Imelda Fat Reducer
7 Days Diet	Extrim Plus 24 Hour Reburn	Fasting Diet
Cosmo Slim	Body Slimming	Body Shaping
Body Creator	BioEmagrecin	3 Days Fit
21 Double Slim	Eight Factor Diet	7 Diet

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), phenolphthalein (a solution used in chemical experiments and a suspected cancer causing agent) and bumetanide (a diuretic). 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 (rapid heart beat), 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