FDA Uncovers Additional Tainted Weight Loss Products

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Agency alerts consumers to the finding of new undeclared drug ingredients
The U.S. Food and Drug Administration is expanding, for the second time, its
countrywide 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 Fat loss Slimming
2 Day Diet Slim Advance GMPSlim
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 Dai Dainhua Slim Tech
7 Day Herbal Slim Mei li Slim Up
7 Days Diet Mei zitang Slim Waist Formula
7 Diet Miaozi Mei Mao Qian Zi Jiao Nang 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
Bio Emagrecim Powerful Slim Superslim
Body Creator Pro Slim Plus Super Slimming
Body Shaping Reduce Weight 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:
- 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 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 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.

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 on these products for consumers and health care professionals can be
found at: http://www.fda.gov/cder/consumerinfo/weight_loss_products.htm

To learn more about the FDA’s initiative against unapproved drugs see the FDA’s

For drug safety information, see: FDA's Drug Safety Initiative.