

The United States: MyNicNaxs, LLC issues voluntary nationwide recall of various dietary supplements due to undeclared active pharmaceutical ingredients (API)

The US Food and Drug Administration (FDA) announces that MyNicNaxs, LLC, Deltona, FL is voluntarily recalling all lots of dietary supplements distributed nationwide to the consumer level. The products have been found to contain undeclared active pharmaceutical ingredients (API). The presence of sildenafil, sibutramine, diclofenac and/or phenolphthalein in the dietary supplements renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall. These products were distributed from Jan 2013 to Dec 2017, though the website <http://www.mynicnaxs.com>. No reports of adverse events have been reported to date.

Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the US market on 21 Dec 2010, after clinical data indicated sibutramine poses an increased risk of heart attack and stroke.

Phenolphthalein is a known carcinogen (cancer causing agent) that was once an ingredient used in over-the-counter laxatives but is no longer approved for marketing in the United States.

Sildenafil is the active pharmaceutical ingredient in Viagra (PDE-5 inhibitor), a drug approved by FDA for the treatment of erectile dysfunction. PDE-5 inhibitors may interact with nitrates found in some prescription drugs (such as nitroglycerin) and can lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

Diclofenac is a non-steroidal anti-inflammatory drugs (NSAIDs) found in FDA-approved drugs that are used to treat pain and inflammation associated with several conditions. NSAIDs could lead to serious gastrointestinal (GI) adverse events such as bleeding, ulceration, and fatal perforation of the stomach and intestines. Patients who are already taking medication that could cause bleeding may increase their risk for bleeding significantly.

The affected products are:

	Product Description	API Found in FDA Lab Results
1.	Platinum Maximum Strength Blue Pill Version; 30 capsules; 500mg each	Sibutramine and Phenolphthalein
2.	Platinum Maximum Strength Blue Pill Version; 30 capsules; 500mg each	Sibutramine and Phenolphthalein
3.	Slimming Plus Advanced Weight Loss; 30 capsules; 500mg each	Sibutramine and Phenolphthalein
4.	African Viagra - sexual performance enhancement product; 4500mg x 2	Sildenafil
5.	GINSENG - sexual performance enhancement product; 300mg/tablet x 10 tablets	Sildenafil

6.	African Superman - sexual performance enhancement product; 2900mg x 8 tablets per blister pack	Sildenafil
7.	Old Chinese - sexual performance enhancement product; 19800mg x 10 capsules	Sildenafil
8.	Lean Extreme Max; 30 capsules; 400mg each	Sibutramine
9.	X-treme Beauty Slim; 30 capsules; 350mg each	Sibutramine
10.	African Superman - Top-Class Permanence Tablet; 2900mg x 8 tablets	Sildenafil
11.	Slim Evolution - 100% Natural Ingredients; 30 capsules; 350mg each	Diclofenac
12.	Meizitang Strong Version capsules packed in a non-flexible clear bottle with a green screw-on top	Sibutramine
13.	Magic Slim capsules packed in a non-flexible white bottle with a white screw-on top	Sibutramine
14.	Slim Xtreme capsules packed in a non-flexible white bottle with a white screw-on top	Sibutramine
15.	Meizi Evolution capsules were packed in a non-flexible clear bottle with a blue screw-on top	Sibutramine
16.	SlimEasy Herbs capsules packed in blister packaging and placed in a white box with black labeling	Sibutramine
17.	Hokkaido - capsules packed in blister packaging in pink box with black labeling	Phenolphthalein
18.	Super Fat Burning Bomb capsules in blister packs, packaged in a red box with black labeling	Sibutramine and Phenolphthalein
19.	FRUTA Bio blister packs, packaged in a yellow/green box with green labeling	Sibutramine and Phenolphthalein
20.	JIANFEIJINDAN Activity Girl - blister packs, packaged in a white/pink box with pink labeling	Sibutramine
21.	Reduce Weight FRUTA PLANTA blister packs, packaged in a yellow/green box with green labeling	Phenolphthalein
22.	Fat Loss Slimming Beauty – 30 capsules in blister packs packaged in yellow/black box -500mg	Sibutramine and Phenolphthalein
23.	Fruta Planta -blister packs packaged in yellow/green box with green labeling	Sibutramine and Phenolphthalein
24.	Botanical Slimming - 100% Natural Soft gel; 30 soft gels; 650mg each packaged in a green bag with yellow and white lettering	
25.	Slim Body - Dietary Supplement;100% Herbal Slimming Formula; 30 capsules; 6x5x300mg blister packs, packaged in blue and red box	

Please refer to the following website in FDA for details:

<https://www.fda.gov/Safety/Recalls/ucm613197.htm>

In Hong Kong, the above products are not registered pharmaceutical products.

Ends/Thursday, Jul 12, 2018

Issued at HKT 15:00