Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

A&H Focal Inc. Issues Nationwide Recall of 29 Products Marketed as Dietary Supplements Due to The Possible Presence of Undeclared Erectile Dysfunction Ingredients

	For	Imme	diate	Release
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March 7, 2017

Contact

Consumers

Henry Choo **(**646) 327-8522

Announcement

A&H Focal Inc. is voluntarily recalling all lots of the following products because many of these products have been historically tested by the FDA and found to contain PDE-5 Inhibitors (i.e. sildenafil, tadalafil, vardenafil, etc.) which is the active ingredient in an FDA-approved drug for erectile dysfunction (ED) making these tainted dietary supplements unapproved drugs.

These undeclared active ingredients poses a threat to consumers because the PDE-5 Inhibitors may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

- Black Ant (4600 mg)
- Indian God Lotion
- Evil Root (1200 mg)
- · Germany Black Gold (2800 mg)
- · Germany Niubian (3000 mg)
- · Hard Ten Days (4500 mg)
- · Lang Yi Hao (Chaonogsuopian) (500 mg)
- · Gold Vigra
- · Clalis
- · Ye Lang Shen (5000 mg)
- Zhansheng Weige Chaoyue Xilishi (2000 mg)

- · Zhonghua Niubian (2000 mg)
- · Stree Overlord (3800 mg)
- Max Man (3000 mg)
- Hu Hu Sheng Wei
- Tiger King
- Viagra 100 (2000 mg)
- · Power V8 Viagra (200 mg)
- · Dadiyongshi Xiangganglongshengwu
- Lien Chan for Seven Days
- Maca Gold (6800 mg)

These products were marketed as dietary supplements for male sexual enhancement. All lots of the listed products sold by A&H Focal Inc. since **January 2014 to present** are included in this recall. The products were mainly sold through Asian Markets located in NJ and NY.

Consumers who have any of the above mentioned products should immediately stop use of the product and properly discard. If you have further distributed this product please notify those individuals of this recall.

Consumers with questions regarding this recall can contact Mr. Henry Choo by calling 646-327-8522, Monday through Saturday, 9am-6pm, EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: <u>www.fda.gov/medwatch/report.htm</u> (http://www.fda.gov/medwatch/report.htm)
- Regular Mail or FAX: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request reporting form, then complete and return to the address on the pre-addresses form, or submit by fax to 1-800-FDA-0178.

This recall and market action are being conducted with the knowledge of the U.S. Food and Drug Administration.

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