

Hidden Risks of Erectile Dysfunction “Treatments” Sold Online

Men looking online for “dietary supplements” to treat erectile dysfunction (ED) or enhance their sexual performance should beware: these products may contain prescription drugs or other undisclosed ingredients that can be harmful.

“The number of these problematic products available on the Internet appears to be increasing,” says Michael Levy, director of the Food and Drug Administration’s (FDA) Division of New Drugs and Labeling Compliance. The division is part of the Office of Compliance (OOC) in the agency’s Center for Drug Evaluation and Research (CDER).

Many consumers perceive these products as completely safe because they are often sold with labeling, suggesting that they are all-natural alternatives to prescription drug products that have been approved by FDA for treating ED.

But these products may be laced with potentially hazardous ingredients that aren’t noted on the label.

Since 2004, FDA has become aware of several such “dietary supplements” (see sidebar for list).

Viagra Ingredient Found

Working with other FDA components, the division’s Internet and Health Fraud Team led an Internet survey in which more than one-third of purchased “dietary supplements” claiming to spur sexual enhancement or treat ED contained undisclosed prescription drug ingredients or similar substances.

Six of the 17 products contained sildenafil (the active ingredient in Viagra) or a substance similar to either sildenafil or vardenafil. Vardenafil is the active ingredient in Levitra, another FDA-approved prescription drug that treats ED.

Mark Hirsch, a medical team Leader in CDER’s Division of Reproductive and Urologic Products, says this undisclosed presence of prescription drug ingredients—and similar compounds known as analogs of the drugs—can lead to serious side effects in users.

Dangerous Interactions

“These products may interact in dangerous ways with drugs that a consumer is already taking,” Hirsch says. For example, taking sildenafil in addition to certain prescription drugs containing nitrates may lower blood pressure to an unsafe level.

People with diabetes, high blood pressure, high cholesterol,



Online Products to Avoid

Since 2004, FDA has identified several products sold online as so-called “dietary supplements” for treating erectile dysfunction and enhancing sexual performance. These products have contained potentially harmful, undeclared ingredients. Included among them are

- Actra-Rx
- Actra-Sx
- Libidus
- Nasutra
- Neophase
- Vigor-25
- Yilishen
- Zimaxx
- 4EVERON
- Liviro3
- Lycium Barbarum L.
- Adam Free
- Rhino V Max
- V.Max
- True Man
- Energy Max
- HS Joy of Love
- NaturalUp
- Blue Steel
- Ereextra
- Super Shanghai
- Strong Testis
- Shanghai Ultra
- Shanghai Ultra X
- Lady Shanghai
- Shanghai Regular, also marketed as Shanghai Chaojimengnan
- Hero
- Naturalë Super Plus
- Xiadafil VIP tablets (Lots 6K029 and 6K209-SEI only)

or heart disease are often prescribed drugs containing nitrates, and men with these conditions commonly suffer from ED, Hirsch says. “Those are factors that doctors consider when prescribing approved ED treatments.”

Preventive Measures

Levy says FDA has determined that many of these products or their active ingredients are imported into the United States from other countries.

“FDA is working closely with U.S. Customs and Border Protection to develop a more effective network to successfully screen and stop these shipments from entering U.S. commerce,” says Huascar Batista, team leader of OOC’s Import-Export Team.

“FDA uses all of its enforcement

powers—including warning letters, seizures, injunctions, import alerts, and criminal prosecution—to protect consumers against these products,” says Levy. Follow-up investigations continue to identify multiple problem products, resulting in additional import alerts, recalls, and seizure actions.

In 2008, U.S. Marshals, at FDA’s request, seized products from two different firms that contained undeclared active ingredients found in FDA-approved prescription drugs for ED, or similar substances.

In April 2008, they seized more than 14,000 dosages of products known as Shanghai Regular, Shanghai Ultra, Super Shanghai, Naturalë Super Plus, and Lady Shanghai. The seized products, valued at more than

\$100,000, originated in China and were packaged and distributed by Shangai Distributors Inc. of Coamo, Puerto Rico.

In July 2008, the Marshals seized specific lots of illegal Xiadafil VIP tablets distributed by SEI Pharmaceuticals Inc. (SEI) of Miami, Fla. The total worth of the seized tablets neared \$74,000.

In both cases, the firms prompted FDA enforcement by failing to act after being notified of the potential adverse health risks posed by the products.

FDA is also evaluating innovative ways to educate consumers about the risks of buying such sexual enhancement products and other drugs online. [FDA](#)

This article appears on FDA’s Consumer Health Information Web page (www.fda.gov/consumer), which features the latest updates on FDA-regulated products. Sign up for free e-mail subscriptions at www.fda.gov/consumer/consumerenews.html.

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FDA Issues Health Risk Alert for ‘True Man’ and ‘Energy Max’ Products
www.fda.gov/bbs/topics/NEWS/2007/NEW01633.html

FDA Requests Recall of ‘True Man Sexual Energy,’ ‘Energy Max’ Dietary Supplements
www.fda.gov/bbs/topics/NEWS/2007/NEW01737.html

FDA Warns Consumers About Dangerous Ingredients in “Dietary Supplements” Promoted for Sexual Enhancement
www.fda.gov/bbs/topics/NEWS/2006/NEW01409.html

FDA Warns Consumers Not to Use “Blue Steel” and “Hero” Products
www.fda.gov/bbs/topics/NEWS/2008/NEW01809.html