Extenze Tablets: Recall

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: FDA notified Biotab Nutraceuticals, Inc. that two lots of counterfeit product purporting to be Extenze contain undeclared drug ingredients. Specifically, lot 0709241 contains tadalafil and sildenafil, and lot 0509075 contains tadalafil and sibutramine.

Tadalafil and sildenafil are drugs used to treat erectile dysfunction (ED). These drugs 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. ED is a common problem in men with these conditions, and consumers may seek Extenze to enhance sexual performance.

Sibutramine is a controlled substance that was withdrawn from the market in October 2010 for safety reasons. Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

BACKGROUND: The counterfeit products are sold at retail nationwide in the form of carded four-packs (lot 0709241) and in the form of a box of thirty tablets divided into two fifteen tablet blister packs (lot 0509075). It is possible that there may be other counterfeit products on the market that have yet to be identified.

RECOMMENDATION: Consumers in possession of product from the lots in question only should return any unused product.

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/22/2011 - Press Release [3] - Biotab Nutraceuticals]

SOURCE [4]

Source URL (retrieved on *12/22/2014 - 6:27am*):
http://www.mdtmag.com/news/2011/02/extenze-tablets-recall

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[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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