



Missouri Department of Health and Senior Services Recall Alert

The Missouri Department of Health and Senior Services received the following recall of EXTENZE nutritional supplement tablets containing lot numbers 0709241 and 0509075. The products are sold at retail stores nationwide.

BIOTAB NUTRACEUTICALS, INC. Issues a Voluntary Recall of Specific Lots of the Nutritional Supplement EXTENZE (Men's Regular)

Contact:

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FOR IMMEDIATE RELEASE - February 22, 2011 -Biotab Nutraceuticals, Inc. ("Biotab") is conducting a voluntary recall of two lots of EXTENZE nutritional supplement tablets. Some packages bearing lot numbers 0709241 and 0509075 are counterfeit products containing undeclared drug ingredients that can pose a serious risk to health.

Biotab learned about the problem after being notified by the Food and Drug Administration (FDA) that two lots of counterfeit product purporting to be EXTENZE contain undeclared drug ingredients. More specifically, lot 0709241 contains tadalafil and sildenafil, and lot 0509075 contains tadalafil and sibutramine. 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).

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Sibutramine is a controlled substance that was withdrawn from the market in October 2010 for safety reasons.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.

The counterfeit Extenze product is not manufactured, distributed or packaged by Biotab, but is falsely marked with the same lot numbers used by Biotab for its genuine product. Because it is very difficult to distinguish the counterfeit from the genuine product, Biotab decided to conduct this voluntary recall of the two affected lots. It is possible that there may be other counterfeit products on the market that have yet to be identified.

Consumers in possession of product from the lots in question only should return any unused product to its immediate supplier for a direct refund. Customers with questions can call (626) 775-6334 Monday through Friday between 9 a.m. and 4 p.m. for further instructions or information with respect to the return and refund process. Additionally, Biotab will refund the supplier for any genuine (non-counterfeit) product returned to it.

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

- Online: <http://www.fda.gov/MedWatch/report.htm>⁹
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>¹⁰. Mail to the address on the pre-addressed form.
- Fax: 1-800-FDA-0178

Biotab is committed to protecting the market place and its customers from counterfeit and adulterated product purporting to be authentic Extenze. It has been avidly policing the marketplace but some pirate product does get through US Customs. We are fully willing to engage in this voluntary recall in order to avoid customer confusion with respect to counterfeit products that falsely use the Biotab lot numbers that are the same as the authentic product. We will continue to cooperate with the FDA in order to ensure that all of our customers can rely on only finding genuine Extenze on the shelves of retailers. However, one failsafe method for retailers to adopt is to only purchase the product from Biotab or its limited authorized distributors. This practice should avoid the unwitting purchase of counterfeit products that are not properly labeled and that come from sources that are not mindful of customer safety.

This recall is being conducted with the knowledge and gratitude of the U.S. Food and Drug Administration.