Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: February 23, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
ASG

SUBJECT: Biotab Nutraceuticals, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; Two lots of EXTENZE nutritional supplement tablets due to counterfeit products containing undeclared drug ingredients that can pose a serious risk to health; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. 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). Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

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

Contact:
Customer Service: Department JM
(626) 775-6334

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[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2]. 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.

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