



Mitchell E. Daniels, Jr.
Governor

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

DATE: February 27, 2012

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

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

SUBJECT: Regeneca, Inc. Issues a Voluntary Nationwide Recall of All Lots of Single Capsule RegenErect Because of Potential Health Risks

SUGGESTED

ACTION: **Unclassified Recall: Regeneca, Inc. announced it is conducting a voluntary nationwide recall of all lots of single capsule packet RegenErect, labeled as a dietary supplement. Through independent lab analysis has confirmed the presence of Tadalafil making these products unapproved new drugs. Regeneca, Inc. advises any customers in possession of the RegenErect product above to return any unused product for an exchange, or a full refund, to the company directly. Customers can call (800) 690-6958 for instructions on the return and exchange/refund process. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product. If any recalled products are found, please notify this office at 317-233-7360.**

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.

Regeneca, Inc. Issues a Voluntary Nationwide Recall of All Lots of Single Capsule RegenErect Because of Potential Health Risks

Contact:
Consumer:
(800) 690-6958

FOR IMMEDIATE RELEASE – February 24, 2012 - (GLOBE NEWSWIRE) -- Regeneca, Inc. (Pink Sheets:RGNA) announced today that it is conducting a voluntary nationwide recall of all lots of single capsule packet RegenErect, labeled as a dietary supplement. The company, through independent lab analysis has confirmed the presence of Tadalafil making these products

unapproved new drugs. Tadalafil is an FDA-approved drug used as treatment for male Erectile Dysfunction (ED). The active drug ingredient is not listed on the label for these products.

Use of these products may pose a threat to consumers because it 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 these types of products to enhance sexual performance.

Regeneca, Inc. has distributed RegenErect via sales made over the internet to consumers in the United States of America and Puerto Rico, and given as samples at public events.

RegenErect, is a blue capsule sold individually in foil packets with a UPC code of 816860010055. Regeneca, Inc. is committed to improving its products and avoiding future recall issues by improving its existing testing procedures.

Regeneca, Inc. advises any customers in possession of the RegenErect product above to return any unused product for an exchange, or a full refund, to the company directly. Customers can call (800) 690-6958 (Monday through Friday from 8am to 6pm Pacific Time) for instructions on the return and exchange/refund process. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

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

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

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

Contact:
Customer Service (800) 690-6958

Regeneca, Inc. Issues a Voluntary Nationwide Recall of All Lots of Single Capsule RegenErect Because of Potential Health Risks Photo:

