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 13, 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 a Specific Lot of RegenArouse Because of Potential Health Risks

SUGGESTED ACTION: **Unclassified Recall; Regeneca, Inc. announced today that it is conducting a voluntary nationwide recall of RegenArouse, a pink capsule sold individually in foil packets, Lot Number 130100 with the expiration date of 12/5/2013 and a UPC code of 816860010079. FDA lab analysis has confirmed the presence of Tadalafil making these products unapproved new drugs. 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. Regeneca, Inc. has distributed RegenArouse via sales made over the internet to consumers in the United States of America and Puerto Rico between November 29, 2011 and February 10, 2012. 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.

Regeneca, Inc. Issues A Voluntary Nationwide Recall Of A Specific Lot Of RegenArouse Because Of Potential Health Risks

Contact:
800-690-6958

FOR IMMEDIATE RELEASE - February 10, 2012 - Regeneca, Inc. announced today that it is conducting a voluntary nationwide recall of RegenArouse, Lot Number 130100, because FDA 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. FDA has advised that consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. FDA has advised that 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 RegenArouse via sales made over the internet to consumers in the United States of America and Puerto Rico between November 29, 2011 and February 10, 2012.

RegenArouse, Lot Number 130100, is a pink capsule sold individually in foil packets, with the expiration date of 12/5/2013 and a UPC code of 816860010079. Regeneca, Inc. had this specific lot of RegenArouse capsules tested at a testing facility and had received a report indicating that no PDE-5 inhibitors or any of their analogues were detected in the capsules. The Company learned today that there was an error on this test and has thus made the decision to issue a voluntary nationwide recall on this lot of RegenArouse. 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 RegenArouse product matching the lot number 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.

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: http://www.fda.gov/MedWatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://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.

Regeneca, Inc. Issues A Voluntary Nationwide Recall Of A Specific Lot Of RegenArouse because Of Potential Health Risks Photos: