Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: November 18, 2013

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

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

SUBJECT: Vitality Research Labs, LLC [Drug]

AFFECTED PRODUCT: **VitaliKOR Fast Acting, lots K58Q and F50Q**

SUMMARY: **Unclassified Recall; Vitality Research Labs, LLC, the repackager of the VitaliKOR Products, is voluntarily recalling lots K58Q and F50Q of VitaliKOR Fast Acting to the consumer level. FDA laboratory analysis on VitaliKOR has determined that this product contains undeclared Vardenafil and Tadalafil. Vardenafil and Tadalafil are active ingredients of FDA-approved drugs used to treat erectile dysfunction (ED), making VitaliKOR Fast Acting an unapproved drug. The undeclared active ingredients poses a threat to consumers because Vardenafil and Tadalafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to unsafe levels.**

This product is marketed as an all-natural nutritional supplement for sexual enhancement and packaged in chip board exterior carton containing clear plastic bottles with forty (40) light blue capsules and were sold nationwide through various internet websites and at retail stores. The number of individual units affected by the recall is 66,090. The lots were produced in January and July of 2013. Vitality Research Labs has discontinued distribution and sales of these lots.

SUGGESTED ACTION: **Recommend notification of affected parties by phone, fax, or e-mail. Consumers should not consume these lots and should return them to their place of purchase for credit. Vitality Research Labs, LLC is notifying its distributors and consumers by email and is arranging for credit of the entire recalled product. Consumers with questions should contact the company at 1-855-424-1954 or via e-mail at customercare@vitalikor Monday - Friday, 8:30 am - 5:00 pm, PST. Consumers should contact their healthcare provider if they have experienced any problems that may be related to taking this unapproved drug. Furthermore, if any recalled products are found, please notify this office at 317-233-3213.**

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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

Vitality Research Labs, LLC, Issues Immediate Voluntary Nationwide Recall of "VitaliKOR Fast Acting" Marketed as a Dietary Supplement, Due to Undeclared Active Ingredients

Contact:
Consumer:
(855) 424-1954
Email: customercare@vitalikor

FOR IMMEDIATE RELEASE - November 13, 2013 – Vitality Research Labs, LLC, the repackager of the VitaliKOR Products, is voluntarily recalling lots K58Q and F50Q of VitaliKOR Fast Acting to the consumer level. FDA laboratory analysis on VitaliKOR has determined that this product contains undeclared Vardenafil and Tadalafil. Vardenafil and Tadalafil are active ingredients of FDA-approved drugs used to treat erectile dysfunction (ED), making VitaliKOR Fast Acting an unapproved drug.

The undeclared active ingredients poses a threat to consumers because Vardenafil and Tadalafil may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to unsafe levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, the product may cause side effects, such as headaches and flushing.

This product is marketed as an all-natural nutritional supplement for sexual enhancement and packaged in chip board exterior carton containing clear plastic bottles with forty (40) light blue capsules and were sold nationwide through various internet websites and at retail stores. The number of individual units affected by the recall is 66,090. The lots were produced in January and July of 2013. Vitality Research Labs has discontinued distribution and sales of these lots.

Consumers should not consume these lots of VitaliKOR Fast Acting and should return the products immediately to the place of purchase for credit. Vitality Research Labs, LLC is notifying its distributors and consumers by email and is arranging for credit of the entire recalled product. Consumers/distributors/retailers that have VitaliKOR for the lots identified for recall should return to place of purchase.

Consumers with questions regarding this recall should contact Vitality Research Labs at 1-855-424-1954 or via e-mail at customercare@vitalikor Monday - Friday, 8:30 am - 5:00 pm, PST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this unapproved drug. Adverse reactions or quality problems experienced with the use of this product 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[1]

- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

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

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