Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 8, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: **Regeneca Worldwide a division of VivaCeuticals, Inc. – RECALL [Drug]**

AFFECTED PRODUCT: **RegenESlim appetite control dietary supplement**

SUMMARY: **Unclassified Recall; This recall has been initiated because FDA analysis confirmed the presence of DMAA.**

The recalled product is RegenESlim appetite control dietary supplement from lot # EX0616R15814 and lot #11414RE5516 and it is packaged in approximately 3 ½" by 3" green and white sachets that contain 2 capsules, with the name RegeneSlim displayed prominently on the front of the sachet.

RegeneSlim is purchased by and distributed through a direct sales force within the United States and Puerto Rico, and through online sales, for both personal consumption and retail sales.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions may contact the company at 1-949-281-2600 between the hours of 9 a.m. and 6 p.m. PDT.**

****

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 Worldwide, A Division Of Vivaceuticals, Inc Voluntarily Recalls RegenESlim Appetite Control Capsules Due To The Presence Of DMAA That May Pose Possible Health Risk

Contact
Consumer:
949-281-2600

Media:
949-281-2600

FOR IMMEDIATE RELEASE – August 6, 2014 – Regeneca Worldwide a division of VivaCeuticals, Inc. Las Vegas, NV is conducting a voluntary nationwide recall of its RegenESlim appetite control dietary supplement from lot # EX0616R15814 and lot #11414RE5516 because FDA analysis confirmed the presence of DMAA. DMAA is also known as 1,3-dimethylamylamine, methylhexanamine, or geranium extract. DMAA is commonly used as a stimulant, pre-workout, and weight loss ingredient in dietary supplement products. The Food and Drug Administration (FDA) has warned that DMAA is potentially dangerous to health as it can narrow blood vessels and arteries, which can cause a rise in blood pressure or other cardiovascular problems such as shortness of breath, arrhythmias, tightening in the chest, and heart attack.

RegeneSlim is purchased by and distributed through a direct sales force within the United States and Puerto Rico, and through online sales, for both personal consumption and retail sales.

RegeneSlim is packaged in approximately 3 ½" by 3" green and white sachets that contain 2 capsules, with the name RegeneSlim displayed prominently on the front of the sachet.

There have been no illnesses reported to date.

This voluntary recall was the result of FDA analysis confirming the presence of DMAA in RegeneSlim and our company's sampling. The company continues their investigation as to what caused the problem.

Consumers who have purchased RegeneSlim with the above-mentioned lot numbers are advised to immediately stop using the product and are urged to return it to the place of purchase for a full exchange. Consumers with questions may contact the company at 1-949-281-2600 between the hours of 9 a.m. and 6 p.m. PDT. Consumers should contact their physician or healthcare provider if they experience any problems that may be related to taking or using RegeneSlim.

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.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm

Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

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

###