

**Governor
John R.****Lieutenant Governor
Mary Taylor****ODA Director
David T. Daniels****ODH Director
Richard Hodges****Kasich****DATE:** September 2, 2014**TO:** Health Commissioners, Directors of Environment Health and Interested Parties**RE:** Recall announcement (ODA/ODH) 2014-093**Regeneca Worldwide, a Division of Vivaceuticals, Inc Expands the Voluntarily Recall of Regeneslim Appetite Control Capsules Due to the Presence of DMAA that May Pose Possible Health Risk**

Regeneca Worldwide a division of VivaCeuticals, Inc. Las Vegas, NV is expanding the voluntary nationwide recall of its RegeneSlim appetite control dietary supplement to include lot #823230415, lot #EX0616r 15813, 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 ^{1/2}" 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.