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**Governor**  
John R. Kasich

**Lieutenant Governor**  
Mary Taylor

**ODA Director**  
James Zehringer

**ODH Director**  
Theodore E. Wymyslo, M.D.

DT: November 14, 2011

TO: Health Commissioners, Directors of Environmental Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2011-134

**Keime Inc dba Barry's Vitamins Conducts a Nationwide Voluntary Recall  
of Virility Max Dietary Supplement:  
Lot Number 10090571**

November 10, 2011 - Keime Incorporated announced today that it is conducting a voluntary recall of one lot of the company's dietary supplement product sold under the following name: Virility Max. The company has been informed by representatives of the FDA that lab analysis by FDA for Lot 10090571, found the product contained sulfoildenafilafil, an analog of sildenafil. Sildenafil is an active ingredient of an FDA approved drug for erectile dysfunction (ED), making Virility Max an unapproved drug.

The active drug ingredient is not listed on the product label. The undeclared ingredient 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. Additionally, the product may cause side effects, such as headaches and flushing.

Virility Max is used for sexual enhancement. It is distributed in 10 count, white plastic bottles to retail customers in the South Florida area.

No illnesses have been reported to the company to date in connection with this product. Customers who have this product in their possession should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product. Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online [at [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)]<sup>1</sup>
- Regular Mail; use postage-paid, pre-addressed Form FDA 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) <sup>2</sup>
- Fax 1-800-FDA-0178].

Keime Inc., a Florida Corporation, is committed to providing accurate information about its products because of concerns for the health and safety of consumers. This product was purchased from others and not manufactured by Keime Inc. Keime Inc. is working voluntarily with the FDA in the recall process. It sincerely regrets any inconvenience to customers. Consumers should return any unused product to the retail location where they were purchased or contact Keime Inc. directly at 561-368-2070 Monday – Friday, 9 AM to 5 PM EDT.

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