

Governor
John R. KasichLieutenant Governor
Mary TaylorODA Director
David T. DanielsODH Director
Richard Hodges

DATE: December 1, 2016

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

RE: Recall Announcement (ODA/ODH) 2016-154

Megajex Natural Male Sex Enhancer by MS Bionic: Recall - Undeclared Drug Ingredients

ISSUE: MS Bionic, Inc. announced today that it is conducting a voluntary nationwide recall of all lots of Megajex Natural Male Sex Enhancer capsules. FDA analysis has found the product to contain Tadalafil and Sildenafil. Tadalafil and Sildenafil are FDA-approved drugs used as treatment for male Erectile Dysfunction (ED). The active drug ingredients are not listed on the label for this product.

Use of this product may pose a threat to consumers because the undeclared active ingredients 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. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

BACKGROUND: Megajex Natural Male Sex Enhancer is marketed as a dietary supplement for erectile dysfunction. It is packaged in 20 count bottles and sold nationwide.

RECOMMENDATION: MS Bionic, Inc. advises any customers in possession of the Megajex to stop using and return any unused product for a full refund to the company directly. Customers can call 714-470-4352 between the hours of 10 a.m. and 5 p.m. Pacific Standard Time for instructions on the return and refund process. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form 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

[11/29/2016 - Press Release - MS Bionic, Inc.]