Ohio Department of Agriculture
and
Ohio Department of Health

Mike DeWine	Jon Husted	Dorothy Pelanda	Amy Acton, MD
Governor	Lieutenant Governor	ODA Director	ODH Director

DATE: April 9, 2019

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

RE: Recall Announcement (ODA/ODH) 2019-064

SD Import Issues Voluntary Nationwide Recall of Aphrodisiac Capsules Due to Presence of Undeclared Sildenafil

SD Import, LLC is voluntarily recalling all lots of Aphrodisiac, Capsules to the consumer level. The products have been found to be tainted with sildenafil. FDA analysis has found the product to be tainted with sildenafil. Sildenafil is an active pharmaceutical ingredient in FDA approved product used in the treatment of erectile dysfunction. The presence of sildenafil in Aphrodisiac capsules renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Consumers with diabetes, hypertension, high cholesterol or heart disease often take nitrates; consumption of undeclared sildenafil along with nitrates could result in a drop in blood pressure that is life-threatening and could result in serious adverse health consequences. To date, SD Imports, LLC has not received any reports of adverse events related to this recall.

Aphrodisiac capsules are marketed as a dietary supplement for men for sexual enhancement and is packaged in a cardboard box with 12 plastic packs in a box. The product can be identified by UPC Code 644118128135. The product was distributed nationwide to retail stores, and a variety of online websites.

SD Imports, LLC is notifying its distributors and customers by email and arranging for return of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using and return to place of purchase.

Consumers with questions regarding this recall can contact SD Import, LLC by calling 248-850-8523 or e-mail at sdimportsllc@gmail.com Monday- Friday from 10AM-5PM EST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, 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.