

Governor
John R. Kasich

Lieutenant Governor
Mary Taylor

ODA Director
David T. Daniels

ODH Interim Director
Lance D. Himes

DATE: May 8, 2014

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

RE: Recall Announcement (ODA/ODH) 2014-055

Eugene Oregon, Inc. Issues Voluntary Nationwide Recall of African Black Ant, Black Ant, and Mojo Risen Dietary Supplements Which May Contain Undeclared Active Pharmaceutical Ingredients

Eugene Oregon, Inc. of Levittown, Pennsylvania is voluntarily recalling the following products at the consumer level:

Product Name	Identifiable Number	Packaging	Packaging Coloring	Quantity Per Package
African Black Ant	2006-000926	Small boxes inside large box	Red, black, and silver	6 pills per small box, 8 small boxes per large box. 48 pills total per large box.
Black Ant	2006-3627878	Small boxes inside large box	Green	4 pills per small box, 20 small boxes per large box. 80 pills total per large box.
Mojo Risen	All lots. No identifiable number on packaging.	Envelopes inside box	Red and white	2 pills per envelope, 24 envelopes per box. 48 pills total per box.

Eugene Oregon, Inc. is voluntarily conducting this recall because FDA analysis of these products distributed to a third party revealed that the distributed products contained undeclared amounts of the active pharmaceutical ingredients sildenafil and tadalafil—FDA-approved pharmaceutical ingredients used to treat erectile dysfunction. **Conclusive testing has not been done to confirm that the recalled products do, in fact, contain sildenafil and/or tadalafil and this recall is being executed as a precautionary measure. To date, Eugene Oregon, Inc. has not received any reports of adverse events related to this recall.**

Sildenafil and tadalafil can pose a threat to consumers because they can interact with nitrates found in some prescription drugs (such as nitroglycerin), resulting in decreased blood pressure. Nitrates are found in prescription drugs used to treat diabetes, high blood pressure, high cholesterol, and heart disease. Sildenafil and tadalafil can also cause side effects such as headaches and flushing. Eugene Oregon, Inc. has discontinued the distribution of these products and is notifying its distributors by mail of this voluntary recall. Consumers that possess these products should stop using them immediately and can return the products to Eugene Oregon, Inc., 922 S. Woodbourne Rd. #304, Levittown, PA 19057-1001. Consumers with questions regarding this recall can contact Eugene Oregon, Inc. by telephone at 1-800-538-3411 from Monday through Friday between 9:00 a.m. and 5:00 p.m. EST.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these products. Consumers can report adverse reactions or quality control problems to the FDA's MedWatch Adverse Event Reporting program as follows:

- Complete and submit reporting form online at www.fda.gov/medwatch/report.htm; or
- Mail or fax reporting form. Download form at www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form. Complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-1078.

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