

Michael R. Pence Governor

William C. VanNess II, MD State Health Commissioner

DATE:

May 29, 2014

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

Laurie Kidwell, RRT Supervisor

Food Protection Program

SUBJECT:

Eugene Oregon, Inc. -**REVISED** RECALL [Drug]

AFFECTED

PRODUCT:

African Black Ant, Black Ant, Mojo Risen

SUMMARY:

Unclassified Recall; The recall is due to a FDA analysis of these products distributed to

a third party revealed that the distributed products contain undeclared amounts of the

active pharmaceutical ingredients sildenafil and tadalafil.

Eugene Oregon, Inc. of Levittown, Pennsylvania is voluntarily expanding the recall of the following products to the consumer level:

Product Name	Lot Number	Packaging	Packaging Coloring	Quantity Per Package
African Black Ant	All lots	Small boxes inside large box	Red, black, and silver	6 capsules per box, 8 boxes per display unit.
Black Ant	All lots	Small boxes / tins inside large box	Green	4 capsules per small box, 20 boxes display unit. Also packaged in 10 tablets and 10 capsules in a metal tin.
Mojo Risen	All lots	Envelopes inside box	Red and white	2 capsules per envelope, 24 envelopes per display box.

This recall is a revised version of the recall issued on May 5, 2014 and is revised to reflect the recall of <u>ALL LOTS</u> of the recalled products.



The recalled products have been distributed nationwide.

SUGGESTED

ACTION:

For consumer inquiry only. 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.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Eugene Oregon, Inc. Issues Voluntary Nationwide Expansion Of The Recall Of All Lots Of African Black Ant, Black Ant, And Mojo Risen Dietary Supplements Which May Contain Undeclared Active Pharmaceutical Ingredients

Contact:

Consumer: 1-800-538-3411

FOR IMMEDIATE RELEASE - May 28, 2014 (Revised from May 5, 2014) Press Release - Eugene Oregon, Inc. of Levittown, Pennsylvania is voluntarily expanding the recall of the following products to the consumer level:

Product Name	Lot Number	Packaging	Packaging Coloring	Quantity Per Package
African Black Ant	All lots	Small boxes inside large box	Red, black, and silver	6 capsules per box, 8 boxes per display unit.
Black Ant	All lots	Small boxes / tins inside large box	Green	4 capsules per small box, 20 boxes display unit. Also packaged in 10 tablets and 10 capsules in a metal tin.
Mojo Risen	All lots	Envelopes inside box	Red and white	2 capsules per envelope, 24 envelopes per display box.

This recall is a revised version of the recall issued on May 5, 2014 and is revised to reflect the recall of ALL LOTS of the recalled products. Misinformation about the Black Ant product codes and packaging description may have been included in the original press release and this

information is intended to clarify any ambiguity and expand the recall to all lots of all recalled products.

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.

Sildenafil and tadalafil can pose a threat to consumers because they can 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, and heart disease often take nitrates. To date, Eugene Oregon, Inc. has not received any reports of adverse events related to this recall.

These products are marketed as dietary supplements for sexual enhancement and packaged in tins, envelopes, and/or boxes and were distributed to consumers nationwide at retail stores. 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.

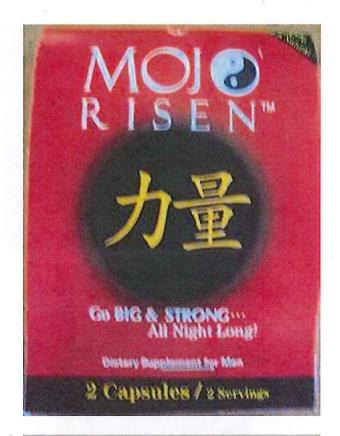
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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 Photos









Mojo fisseriis a safe, revolutionary sexual formula for men that combines ancient Chinese school of thought and modern exence to support sexual starring parformance and pleasure.

Directors: Adults, take only 1 capsule a day a nours before activity. After a mail, For long form best results DO NOT take arrary day. Each desage is good for up to 2 to 3 days.

Supplement Facts

Serving Size: 1 Capture

Amount Per Serving Serv

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+Daily Value not established.

Other Ingredients, Gelatin, silicon Diaxide, Magnasium Stearate

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Suggested relations \$5, 97

Distributed by: Mojo Risen LLC Springville UT 84663

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