

Governor
John R. KasichLieutenant Governor
Mary TaylorODA Director
David T. DanielsODH Director
Theodore E. Wymyslo, M.D.

DATE: November 19, 2013

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

RE: Recall Announcement (ODA/ODH) 2013-132

Fossil Fuel Products, LLC, Issues Voluntary Nationwide Recall of "RezzRX" Due to Undeclared Active Ingredients

Fossil Fuel Products, LLC, is voluntarily recalling lots QL110714A102 (20-count bottles) and QL110408B046 (single blister packs) of "**RezzRX**" to the **consumer** level. Laboratory analysis conducted by the FDA determined the RezzRX lot QL110714A102 (20-count bottles) contains undeclared hydroxylthiohomosildenafil and aminotadalafil and RezzRX lot QL110408B046 (single blister packs) contains undeclared hydroxylthiohomosildenafil. The **products** have been found to **contain hydroxylthiohomosildenafil and aminotadalafil which are active ingredients of FDA approved drugs used to treat erectile dysfunction (ED), making "RezzRX" an unapproved new drug.**

Risk Statement: These undeclared active ingredients pose a threat to consumers because use of these products have the potential to interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to unsafe levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. Additionally, may cause side effects, such as headaches and flushing. **Fossil Fuel Products, LLC**, has not received any reports of adverse events related to this recall.

The product is **marketed as a natural supplement for sexual enhancement** and is packaged in single blister retail cards containing 1 yellow capsule and 20-count white bottles containing 20 yellow capsules. The affected **RezzRX** lots include the following **lot numbers and expiration dates** [QL110714A102 Exp 11/2013 and QL110408B046 Exp 06/2015]. **RezzRX** was distributed nationwide through various websites and retail stores in Georgia.

Fossil Fuel Products, LLC, is notifying its distributors and customers by **direct mail and email** and is arranging for **return** of all recalled products. **Consumers/distributors/retailers** that have **product** which is being recalled should **stop using/return to place of purchase/discard/contact their doctor, etc.**

Consumers with questions regarding this recall can contact **Fossil Fuel Products, LLC**, by **1-877-773-9979** or info@rezzrx.com, **Monday-Friday, 9:00 am- 5:00 pm, 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 experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online:** www.fda.gov/medwatch/report.htm1
- **Regular Mail:** use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm2. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

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