



# Ohio Department of Agriculture and Ohio Department of Health



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John R. Kasich

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Mary Taylor

**ODA Director**  
David T. Daniels

**ODH Director**  
Theodore E. Wymyslo, M.D.

DATE: April 12, 2013  
TO: Health Commissioners, Directors of Environment Health and Interested Parties  
RE: Recall Announcement (ODA/ODH) 2013-048

## **Affirm XL, Inc Issues a Voluntary Nationwide Recall of Affirm XL Dietary Supplement Tablet, Lot 1190001 Due to Potential Health Risk**

April 10, 2013 - Affirm XL, Inc announced that it is conducting a voluntary nationwide recall of the company's dietary supplement sold under the brand name Affirm XL specific to lot number 1190001.

Affirm XL, Inc. is conducting a voluntary recall to the consumer level after FDA lab analysis testing found the product to contain an analogue of sildenafil. Sildenafil is an active ingredient used in an FDA-approved product for the treatment of male Erectile Dysfunction (ED). The active drug ingredient is not listed on the label for this product.

Affirm XL Tablet is marketed as a dietary supplement for sexual enhancement. It is sold nationwide in 10 count blister packs and single pill packs.

There are no illnesses associated with this product.

Use of this product may pose a threat to consumers because the analogue 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.

Affirm XL, Inc advises any customers in possession of the Affirm XL product matching the lot number above to return any unused product for a full refund to the company directly. Customers can call 1-800-385-0738 (Monday to Sunday 8 am to 5 pm pacific standard time) for instructions on the return and refund process.

Affirm XL, Inc is committed to improving its products and avoiding future recall issues by sourcing higher quality raw ingredients and expanding testing. Affirm XL, Inc promises its customers the highest possible quality and welcomes the recall process as further evidence of our commitment to our brands, products and consumers.

Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: <http://www.fda.gov/MedWatch/report.htm>
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: <http://www.fda.gov/MedWatch/getforms.htm>. 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.