Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 11, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Affirm XL, Inc Recall

SUGGESTED ACTION: **Unclassified Recall; FDA lab analysis testing found the product to contain an analogue of sildenafil. Sildenafil is an active ingredient and is not listed on the label for this product; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. 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. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

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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.

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

Contact
Consumer:
1-800-385-0738
info@affirmxl.com

FOR IMMEDIATE RELEASE - April 10, 2013 - Affirm XL, Inc announced today 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[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2]. 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.

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