Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 3, 2013

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

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

SUBJECT: American Lifestyle Recall

SUGGESTED ACTION: **Unclassified Recall; All lots of Vicerex UPC 893490820087 and Black Ant UPC 4026666142546. Laboratory analysis conducted by the FDA has determined the Vicerex product contains undeclared tadalafil and the Black Ant product contains undeclared sildenafil; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. The products were distributed worldwide by American Lifestyle by on-line sales and retail. 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.

American Lifestyle Issues a Worldwide Voluntary Recall of Vicerex Capsules and Black Ant Capsules, Marketed as a Dietary Supplement, Due to Undeclared Active Ingredients

Contact
Consumer:
American Lifestyle
585-586-1878

FOR IMMEDIATE RELEASE - May 1, 2013 - American Lifestyle is announcing that it is conducting a voluntary recall of all lots of Vicerex UPC 893490820087 and Black Ant UPC 4026666142546. Laboratory analysis conducted by the FDA has determined the Vicerex product contains undeclared tadalafil and the Black Ant product contains undeclared sildenafil. Tadalafil and sildenafil are FDA-Approved drugs used to treat male erectile dysfunction (ED), making the Vicerex and the Black Ant products unapproved new drugs.

Risk Statement: These undeclared active ingredients poses a threat to consumers because tadalafil and sildenafil 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. No Adverse events have been reported related to this recall.

Vicerex is sold in blister packs containing ten (10) capsules and Black Ant is sold in a box containing four (4) individually wrapped capsules. The product is distributed worldwide by American Lifestyle by on-line sales and retail. The products are being promoted for increasing desire and sexual performance. The products are sold without medical prescription.

American Lifestyle is notifying its customers by telephone and email and is arranging for return of all recalled products. Consumers who have purchased Vicerex or Black Ant capsules are urged to immediately discontinue their use and return the product to their place of purchase or directly to American Lifestyle, 640 Kreag Road, Pittsford, NY 14534. Consumers are asked to have order number or proof of purchase.

Consumers with questions regarding this recall may contact American Lifestyle at 585-586-1878 Monday through Friday 7 am to 3 pm EST.

Consumers who have purchased any of these products and have any of the mentioned medical illnesses should consult their health care providers.

Adverse reaction or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program 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.

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