Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: September 18, 2012

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

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

SUBJECT: Body Basics Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; A voluntary nationwide recall of ACTRA-Sx 500 Dietary Supplement Capsules, Lot 008-A, Expiration December 2013 due to presence of Sildenafil Citrate making this product unapproved new drugs; 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. Body Basics Inc. has distributed ACTRA-Sx 500 via sales made to independent distributors in the Los Angeles area and directly to some consumers. Body Basics Inc. does not distribute or sell this product via the internet. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Body Basics Inc. Issues a Voluntary Nationwide Recall of ACTRA-Sx 500 Capsules, Lot 008-A, due to Potential Health Risks

Contact

Consumer:
800-595-2718

FOR IMMEDIATE RELEASE - September 12, 2012 - Body Basics Inc. announced today that it is conducting a voluntary nationwide recall of ACTRA-Sx 500 Dietary Supplement Capsules, Lot 008-A, Expiration December 2013. The Company, through independent lab analysis has

confirmed the presence of Sildenafil Citrate making this product unapproved new drugs. Sildenafil is the active ingredient used in an FDA approved drug to treat Erectile Dysfunction (ED). The active drug ingredient is not listed on the label for this product.

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

Body Basics Inc. has distributed ACTRA-Sx 500 via sales made to independent distributors in the Los Angeles area and directly to some consumers. Body Basics Inc. does not distribute or sell this product via the internet.

ACTRA-Sx 500, is a purple and gold capsule sold in bottles of 5 count with a UPC code of 830733002015. Body Basics Inc. is committed to improving its products and avoiding future recall issues by improving its existing testing procedures.

Body Basics Inc. is warning distributors and consumers who purchased this product not to distribute, sell or consume this product. Although Body Basics voluntarily ceased distribution of this product in November 2011, if consumers are still holding this product bearing that lot number and expiration date, please cease all use of this product immediately. Any customer in possession of the ACTRA-Sx 500 product above is advised to return any unused product for a full refund to the Company directly.

As there is no practical or economical way to determine whether the product you purchased is so contaminated, you are encouraged to contact Body Basics Inc. at 800-595-2718 for instructions and return policy, or, if you have any other questions or concerns. To date no known complications or other health problems have been reported by anyone to the Company.

Any 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.htm[1]
- **Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at:** www.fda.gov/MedWatch/getforms.htm.[2] **Mail to address on the pre-addressed form.**
- **Fax: 1-800-FDA-0178**

This voluntary recall is beings made with the knowledge of the U.S. Food and Drug Administration

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RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]