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: August 16, 2010

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

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

SUBJECT: Prolatis' Recall

SUGGESTED ACTION: **Unclassified Recall; Prolatis' contains Sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used as treatment for male Erectile Dysfunction (ED), making Prolatis' an unapproved drug; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. Prolatis' is sold nationwide in double blister packs and 40 count bottles. Detail information is not available at this time. In addition, if any recalled product is found, please notify this office at 317-233-7360.

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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.

Prolatis' Issues a Voluntary Nationwide Recall of its product Prolatis' Marketed as Dietary Supplement prior to August 9, 2010

Contact:
Prolatis'
1-877-286-5056

FOR IMMEDIATE RELEASE - August 9, 2010 – Prolatis' – Salt Lake City, UT announced today that it is conducting a voluntary nationwide recall of the company's product sold under the name Prolatis'. Prolatis' is conducting a voluntary recall after being informed by the Food and Drug Administration (FDA) that lab analysis has found Prolatis' to contain Sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used as treatment for male Erectile Dysfunction (ED), making Prolatis' an unapproved drug. The active drug ingredient is not listed on the product label. Product manufactured prior to August 9, 2010 is included in this recall. Prolatis' is sold nationwide in double blister packs and 40 count bottles.

This recall is being conducted as a precautionary measure. No illnesses or adverse effects have been reported to the company to date in connection with this product.

The undeclared ingredient 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.

Prolatis' advises any customer in possession of Prolatis' to return the product for a full credit towards the new product. Customers can call 1.877.286.5056 for instructions on the return and credit process.

Any adverse events that may be related to the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm[9]], by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm[10]] by mail [to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178].

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