

Mitchell E. Daniels, Jr. Governor

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

DATE:

April 14, 2010

TO:

All Local Health Departments

Attn: Chief Food Inspection Officer

FROM:

A. Scott Gilliam, MBA, CP-FS

Director, Food Protection Program

**SUBJECT:** 

Atlas Operations, Inc. Recall

## **SUGGESTED**

ACTION: Unclassified Recall; Dietary supplements for sexual enhancement to include Stamin It, Erectzia, and Vigor 100 undeclared ingredient may pose a threat to the consumer; 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. The recalled products are in capsule form and may be packaged in blisters, pouches or 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.

## 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.

Atlas Operations, Inc. Announces Expansion of its Nationwide Voluntary Recall of Specific Lots of Sexual Enhancement Products Marketed as Dietary Supplements

## **Company Contact:**

Daniel Kinney 954-788-1200

**FOR IMMEDIATE RELEASE** – April 12, 2010 – Pompano Beach, FL – Atlas Operations, Inc. announced today that it is expanding its December 12, 2009 voluntary nationwide recall of the company's dietary supplements for sexual enhancement to include Stamin It, Erectzia, and Vigor 100.

These products were sold as dietary supplements throughout the United States. Atlas Operations, Inc. is conducting a voluntary recall after being informed by the Food and Drug Administration (FDA) that lab analyses found that the products to contain Sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used in the treatment of male Erectile Dysfunction (ED), making these products unapproved new drugs. The active drug ingredient is not listed on the product label.

The undeclared ingredient may pose a threat to the consumer because the interaction of the analogue with some prescription drugs (such as nitroglycerin) may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take other prescription drugs. Erectile Dysfunction is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

The recalled products are in capsule form and may be packaged in blisters, pouches or bottles. All expiration dates of the products are included in this recall.

## Complete List of Recalled Products and Lot Numbers

PRODUCT	LOT NUMBER*
	###-705-##
72 Hours (all strengths)	###-706-##
Amour Again for Him	###-705-##
Arousin	###-705-##
Clyamax	###-705-##
	###-807-##
Depth Charge	##-807-##
100 Television   100 Te	###-705-##
Enhancement	###-706-##
	###-705-##
Erectzia	##-705-##
Erexa	###-705-##
	###-705-##
Ere-xxx by Elite Body	##-705-##
Ere-xxx by Maxi Elit	###-705-##
	-
Erousa	###-705-##
Affairk Affair (1988) (7) a backlander de eens kan banka y she'y a been maa ee a bay ees oo ask't ke'n yn ko	###-705-##
Ezerex	###-706-##

e 1884 talah kabir dari kebuda 19 a 1 adik abasha sebas 1 dari menasasah adik a 1 a a menasasah a 1 menagan yag	###-706-##
Finally On Demand	###-700-##
	###-705-##
	###-520A-##
Libiplus	###-520B-##
	###-706-##
	###-520A-##
Love Fuel	###-520B-##
Rainbow Rocket	###-706-##
Red Hot Sex	###-705-##
Sexual Surge	###-705-##
	###-705-##
	###-520A-##
Stamin It	###-520B-##
ANN 1/2	###-705-##
	###-520A-##
Staminil	###-520B-##
Tacktol	###-705-##
Topviril	###-705-##
BECOMES NO COMPANY IN THE PROPERTY OF THE PROP	###-520-##
	###-520A-##
	###-520B-##
Vaxitrol	###-520C-##
Vierect	###-705-##
Vigor 100	###-705-##
Whatz Up Rx	###-706-##
Xtremexcite	###-706-##
	###-705-##
Zenerect	###-779-##

<sup>\*</sup>Consumers can identify recalled products by the 3 or 4 digit code located in the middle of the lot numbers noted above, where "#" represents any alphanumeric digit. Additionally, the lot numbers may or may not contain dashes.

Our laboratories have identified that one of the raw ingredients was tainted with Sulfoaildenafil. Atlas Operations takes this recall very seriously and recommits to the diligent work required in

ensuring its products remain free of any potentially unapproved chemicals. We take the utmost pride in our products' quality control without compromising our customer's health.

We urge consumers who have purchased these products to discontinue their use and return to their place of purchase. You may also return products directly to Atlas Operations. Customers can call Atlas Operations at 1-800-466-4444 Monday through Friday from 9:00 am -5:00 pm EST for instructions on the return and refund process.

It is the position of Atlas Operations, Inc. that we did not in any way knowingly or intentionally violate the law with regard to the distribution of these products.

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

###