Indiana State Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

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

DATE: August 11, 2010

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

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

ASG

SUBJECT: Novacare LLC Recall

SUGGESTED ACTION: **Unclassified Recall; Products appear to contain sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used as treatment for male Erectile Dysfunction. "Sulfoaildenafil" is not declared on the product labels; 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 listed above were distributed in bottles and/or "blister cards" to retailers and via internet sales. All lots of the above-named products with manufacture or distribution dates prior to June 17, 2010 are being recalled. 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.

Novacare LLC Conducts Voluntary Nationwide Recall of Products Found to Contain Undeclared Drug Ingredient

Contact:
Janay Jespersen
801-290-1738

FOR IMMEDIATE RELEASE -– Salt Lake City, UT – August 10, 2010 – Novacare LLC announced today that it is conducting a voluntary nationwide recall of products sold under the following names: **Stiff Nights, Aziffa, Size Matters, Erex, Mojo, Hard Drive, Eyeful, Red Magic, Straight Up, Zotrex, Monster Excyte, WOW, Xaitrex, Verect, Prolatis, Xytamax, Maxyte, Libidinal, OMG, OMG45,** and **Zilex (with Golden Spear)**.

Novacare LLC has been informed by representatives of the Food & Drug Administration (FDA) that the products appear to contain sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used as treatment for male Erectile Dysfunction. "Sulfoaildenafil" is not declared on the product labels. The undeclared ingredient 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.

The recalled products listed above were distributed in bottles and/or "blister cards" to retailers and via internet sales. **All lots of the above-named products with manufacture or distribution dates prior to June 17, 2010 are being recalled.**

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 these products.

Customers who have any of the above-named products in their possession should stop using them immediately and contact their physician if they have experienced any problems that may be related to taking these products.

Consumers and healthcare professionals should report any adverse events that may be related to the use of the above-named products to the FDA's Med Watch Adverse Event Reporting Program online at www.fda.gov/medwatch/report.htm[9], by phone 1-800-FDA-1088, or by returning the postage-paid FDA form 3500 which may be downloaded from www.fda.gov/MedWatch/getforms.htm[10] by mail to FDA Med Watch, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787 or fax to 1-800-FDA-0178.

Novacare LLC is conducting this recall with the knowledge of the FDA. Consumers should return any unused product to the place of purchase or contact Novacare LLC directly at 801-290-1738, Monday – Friday, 10 am to 4 pm MDT.

#