



Mitchell E. Daniels, Jr.
Governor

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

DATE: August 25, 2010
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Natural Wellness Recall

SUGGESTED

ACTION: Unclassified Recall; MasXtreme, Lot # 907043, UPC 094922300805; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. MasXtreme is sold in blister packs containing one (1) capsule. The product is distributed nationwide by Natural Wellness Inc. This product is being promoted for increasing desire and sexual performance. The product is sold without medical prescription. 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.

Natural Wellness, Inc. Issues a Nationwide Voluntary Recall of Masxtreme Capsules, Marketed as a Dietary Supplement

Contact:
Alex Treyner
(954) 570-6662

FOR IMMEDIATE RELEASE - August 24, 2010 - Natural Wellness is announcing that it is conducting a nationwide voluntary recall of MasXtreme, Lot # 907043, UPC 094922300805. Laboratory analysis conducted by FDA has determined the product contains undeclared amounts of Aminotadalafil, an analog of tadalafil. Tadalafil is an FDA-Approved drug used to treat erectile dysfunction (ED), making the MasXtreme an unapproved new drug.

Risk Statement: FDA advises that this poses a threat to consumers because aminotadalafil 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.

MasXtreme is sold in blister packs containing one (1) capsule. The product is distributed nationwide by Natural Wellness Inc. This product is being promoted for increasing desire and sexual performance. The product is sold without medical prescription. No adverse events have been reported.

Consumers who have purchased MasXtreme tablets are urged to immediately discontinue their use and return the product to their place of purchase or directly to Natural Wellness Inc. at 440 S Federal Hwy, Suite 107, Deerfield Beach, FL 33441. Consumers with questions regarding this recall may contact the company at 954-570-6662 Monday through Friday 8 am to 4 pm. Consumers who have purchased this product and have medical concerns should consult with 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: www.fda.gov/MedWatch/report.htm⁹. Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm¹⁰. Mail to address on the pre-addressed form. Fax: 1-800-FDA-0178.

This recall is being conducted in cooperation with the U.S. Food and Drug Administration (FDA).

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