



DATE: March 31, 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# 911035; 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 product was distributed nationwide to retailers. 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 Person:
Alex Treyunker
(954) 570-6662

FOR IMMEDIATE RELEASE -- March 30, 2010 - Natural Wellness is warning consumers not to purchase or consume the product known as MasXtreme, Lot# 911035. This product which is being marketed as a dietary supplement contains undeclared amounts of Aildenafil, as well as the drug Phentolamine which is an alpha-adrenergic blocker. Aildenafil is close in structure to Sildenafil and is expected to possess a similar pharmacological and adverse event profile. Sildenafil is the active pharmaceutical ingredient in an FDA-approved drug that is used to treat erectile dysfunction (ED). This may pose a threat to consumers because Aildenafil 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. Common side effects of Phentolamine include arrhythmia (abnormal heart rhythm) and tachycardia (rapid heart beat).

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.

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.htm¹. Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm². 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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