Novacare LLC Products: Recall - Undeclared Drug Ingredient

U.S. Food & Drug Administration

AUDIENCE: Consumers

ISSUE: Novacare LLC was notified by FDA that certain 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.

BACKGROUND: 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.

RECOMMENDATION: Consumers 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[08/10/2010 - Press Release [3] - Novacare LLC]

SOURCE [4]

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http://www.mdtmag.com/news/2010/08/novacare-llc-products-recall-undeclared-drug-ingredient?qt-recent_content=0

Links:

[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm221958.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm222052.htm