RegenArouse: Recall - Undeclared Drug Ingredient

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: Regeneca, Inc. notifed the public of a nationwide recall of RegenArouse, Lot Number 130100. FDA lab analysis confirmed the presence of Tadalafil, an FDA-approved drug used as treatment for male Erectile Dysfunction (ED), making this product unapproved new drug.

Use of this product may pose a threat to consumers because it may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. FDA has advised that consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

BACKGROUND: Regeneca, Inc. distributed RegenArouse via sales made over the internet to consumers in the US and Puerto Rico between November 29, 2011 and February 10, 2012. RegenArouse, Lot Number 130100, is a pink capsule sold individually in foil packets, with the expiration date of 12/5/2013 and a UPC code of 816860010079.

RECOMMENDATION: Regeneca, Inc. advises any customers in possession of the RegenArouse product matching the lot number above to return any unused product for an exchange, or a full refund, to the company directly.

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 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

[02/10/2012 - Press Release [2] - Regeneca, Inc.]

SOURCE [3]

Source URL (retrieved on *01/26/2015 - 1:08pm*):

http://www.mdtmag.com/news/2012/02/regenarouse-recall-undeclared-drug-ingredient

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/Recalls/ucm291546.htm
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm291577.htm