Aromatase Inhibitors in Products Marketed as Dietary Supplements: Recall

U.S. Food & Drug Administration

AUDIENCE: Consumer, Family Practice, Pharmacy

ISSUE: Products marketed as dietary supplements contain aromatase inhibitors, commonly known as “ATD.” Adverse events associated with the use of aromatase inhibitors could include the following: decreased rate of bone maturation and growth, decreased sperm production, infertility, aggressive behavior, adrenal insufficiency, kidney failure, and liver dysfunction. Consumers with liver, kidney, adrenal, or prostate abnormalities are at higher risk for developing adverse events.

BACKGROUND: The FDA concludes that products containing aromatase inhibitors have a reasonable probability of resulting in permanent impairment of a body structure or function in at risk consumers. FDA has notified manufacturers that these products do not meet the definition of a dietary ingredient and therefore the product is in violation of provisions of the Food, Drug and Cosmetic Act. Many of these products are or had been sold nationwide, both in retail stores and via the internet directly to consumers. Some have been discontinued but some online retailers may still have remaining inventory that they are offering for sale.

RECOMMENDATION: Consumers who have any of these products in their possession should stop using it immediately. If consumers experience any adverse side effects due to its consumption they should contact a physician. Photos of the recalled products are available through links on the company press releases, seen below.

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

[09/15/2010 - Press Release [3] - Kilosports, Inc]
[09/13/2010 - Press Release [4] - Genetic Edge Technologies, Inc]
[09/16/2010 - Press Release [5] - Advanced Muscle Science, Inc]
[09/16/2010 - Press Release [6] - Fizogen Precision Technologies, Inc]

[09/16/2010 - Press Release [7] - iForce Nutrition LLC]

SOURCE [8]

Source URL (retrieved on *12/19/2013 - 12:54pm*):
http://www.mdtmag.com/news/2010/09/aromatase-inhibitors-products-marketed-dietary-supplements-recall

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/ucm225847.htm
[4] http://www.fda.gov/Safety/Recalls/ucm225848.htm
[5] http://www.fda.gov/Safety/Recalls/ucm226145.htm
[6] http://www.fda.gov/Safety/Recalls/ucm226109.htm
[7] http://www.fda.gov/Safety/Recalls/ucm226259.htm
[8] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm226343.htm