



Mitchell E. Daniels, Jr.
Governor

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

DATE: September 20, 2010
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Advanced Muscle Science Recall

SUGGESTED

ACTION: Unclassified Recall; All Lot Codes of the company's dietary supplement products sold under the names Arom-X, Arom-X UTT, Arom-XL, 4-AD, and Decavol, which are marketed as Natural Testosterone Boosters and Libido Enhancers; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. These products are sold both individually and as part of promotional "Kits". The recalled products had been sold nationwide, both in retail stores and direct to consumers. 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.

Advanced Muscle Science Issues a Voluntary Nationwide Recall of AROM-X Capsules, AROM-X UTT Liquid, AROM-XL Liquid, 4-AD Capsules and Decavol Capsules Marketed as a Dietary Supplements Containing ATD

Contact:
Greg Martinez at Greg@advancedmusclescience.com

FOR IMMEDIATE RELEASE – Silver Springs, NV -- September 16, 2010 - Advanced Muscle Science, 4590 Deodar St., Silver Springs, Nevada 89429, announced today that it is conducting a voluntary nationwide recall of all Lot Codes of the company's dietary supplement products sold under the names Arom-X, Arom-X UTT, Arom-XL, 4-AD, and Decavol, which are marketed as Natural Testosterone Boosters and Libido Enhancers. The products contain 1,4,6 etioallocholan-dione, also known as ATD, an aromatase inhibitor. These products are sold both individually and as part of promotional "Kits". Advanced Muscle Science is conducting this recall after being informed by representatives of the Food and Drug Administration (FDA) that it is FDA's opinion that 1,4,6 etioallocholan-dione does not meet the definition of a dietary ingredient and therefore the product is in violation of provisions of the Food, Drug and Cosmetic Act.

FDA has requested that Advanced Muscle Science inform consumers that 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. It is FDA's opinion that products containing aromatase inhibitors have a reasonable probability of resulting in permanent impairment of a body structure or function in at risk consumers. Advanced Muscle Science has not received any adverse event reports nor are they aware of any adverse events associated with the use of these products.

Arom-X Capsules had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by Advanced Muscle Science in March of 2009. The product was sold in bottles containing sixty (60) or eighty (80) capsules, offered individually and as part of promotional "Kits" and was manufactured for Advanced Muscle Science.

Arom-X UTT Liquid had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by Advanced Muscle Science in January of 2010. The product was sold as a liquid in 60mL bottles, offered individually and as part of promotional "Kits" and was manufactured for Advanced Muscle Science.

Arom-XL Liquid had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by Advanced Muscle Science in February of 2009. The product was sold in bottles containing one hundred (100) capsules and as a liquid in 120mL bottles, offered individually and as part of promotional "Kits" and was manufactured for Advanced Muscle Science.

4-AD Capsules had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by Advanced Muscle Science in March of 2009. The product was sold in bottles containing sixty (60) capsules, offered individually and as part of promotional "Kits" and was manufactured for Advanced Muscle Science.

Decavol Capsules had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by Advanced Muscle Science in January of 2010. The product was sold in bottles containing sixty-three (63) capsules and was manufactured for Advanced Muscle Science.

Although most of these products were discontinued over a year ago, it has come to the attention of Advanced Muscle Science that some online retailers may still have remaining inventory that they are offering for sale.

Consumers who have the previously described versions of Arom-X Capsules, Arom-X UTT Liquid, Arom-XL Liquid, 4-AD Capsules and Decavol Capsules, in their possession should stop using them immediately. If consumers experience any adverse side effects due to consumption of

any of these products, they should contact a physician right away. Adverse reactions or quality problems experienced with the use of this product may be reported to Advanced Muscle Science or 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 or Fax: 1-800-FDA-0178.

The Company is advising consumers who have Arom-X Capsules, Arom-X UTT Liquid, Arom-XL Liquid, 4-AD Capsules and Decavol Capsules to return any unused portion to the retail location from which it was purchased or if purchased directly from Advanced Muscle Science to return any unused portion to: **Fitness Connection c/o AMS Fulfillment, 350 Faunce Corner Road, North Dartmouth, MA 02747; (800) 854-3891.**

This voluntary recall does not include Arom-X RD, which is sold in a box of blister packs containing sixty (60) tablets and the current version of Arom-X which is sold as a 60mL bottle, neither of which contain 1,4,6 etioallocholan-dione. Consumers with questions regarding this recall can contact the company at 1- (949)916-5544 Monday through Friday 9 AM to 5 PM, PST. Consumers who have purchased this product and have medical concerns should consult with their health care providers.

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

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Photo: Product Labels¹¹