Indiana State Department of Health
An Equal Opportunity Employer

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

ASG

SUBJECT: Fizogen Precision Technologies Recall

SUGGESTED ACTION: **Unclassified Recall; All Lot Codes of the company's dietary supplement product sold under the name Off Cycle II Hardcore which contains 3,17-keto-etiochol-triene (a synonym for ATD an aromatase inhibitor); 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. Off Cycle II Hardcore had been sold nationwide but was discontinued by Fizogen in July of 2009. The product was sold in bottles containing ninety (90) capsules and was manufactured exclusively for Fizogen Precision Technologies. Although the product was discontinued over a year ago, it has come to the attention of Fizogen that some online retailers may still have remaining inventory that they are offering for sale. 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.

Fizogen Precision Technologies, Inc. Issues a Voluntary Nationwide Recall of OFF CYCLE II HARDCORE, a Product Marketed as a Dietary Supplement

Contact:
Patrick Owens
Pat@fizogen-hq.com

FOR IMMEDIATE RELEASE - Wellington, FL - September 15, 2010 - Fizogen Precision Technologies, 3133 Fortune Way, Suite #4, Wellington, FL 33414, announced today that it is conducting a voluntary nationwide recall of all Lot Codes of the company's dietary supplement product sold under the name Off Cycle II Hardcore which contains 3,17-keto-etiochol-triene (a synonym for ATD an aromatase inhibitor). Fizogen Precision Technologies is conducting this recall after being informed by representatives of the Food and Drug Administration (FDA) that they do not believe 3,17-keto-etiochol-triene meets 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 Fizogen 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. 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. Fizogen has not received any adverse event reports nor are they aware of any adverse events associated with the use of this product.

Off Cycle II Hardcore had been sold nationwide but was discontinued by Fizogen in July of 2009. The product was sold in bottles containing ninety (90) capsules and was manufactured exclusively for Fizogen Precision Technologies. Although the product was discontinued over a year ago, it has come to the attention of Fizogen that some online retailers may still have remaining inventory that they are offering for sale.

Consumers who have Off Cycle II Hardcore in their possession should stop using it immediately. If consumers experience any adverse side effects due to its consumption they should contact a physician right away. Adverse reactions 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.htm[9] Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at www.fda.gov/MedWatch/getforms.htm[10] or Fax: 1-800-FDA-0178.

The Company is advising consumers who have purchased Off Cycle II Hardcore to return any unused portion to the retail location from which it was purchased or to the Company directly if it was purchased from the Fizogen Precision Technologies website. Consumers with questions regarding this recall can contact the company at 1-(800)929-4099 Monday through Friday 9 AM to 5 PM, EST. 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).

Photo: Product Labels[11]