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: iForce Nutrition, LLC Recall

SUGGESTED ACTION: **Unclassified Recall; All Lot Codes of the company's dietary supplement product sold under the name Reversitol, which was marketed "for promoting hormonal regulation...," and contains 6-Etioallochol-1,4-Diene-3,17-Dione, also known as 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. Reversitol had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by iForce Nutrition on December 10, 2009. 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.

iForce Nutrition Issues a Voluntary Nationwide Recall of Reversitol a Product Marketed as a Dietary Supplement Containing ATD

Company Contact:
Dave Nelson
info@iforcenutrition.com

FOR IMMEDIATE RELEASE – September 16, 2010 – Vista, CA – Tribravus Enterprises, LLC d/b/a/ iForce Nutrition, LLC, 1305 Hot Spring Way #103, Vista CA 92081, 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 Reversitol, which was marketed "for promoting hormonal regulation…," and contains 6-Etioallochol-1,4-Diene-3,17-Dione, also known as ATD, an aromatase inhibitor. iForce Nutrition is conducting this recall after being informed by representatives of the Food and Drug Administration (FDA) that it is FDA's opinion that 6-Etioallochol-1,4-Diene-3,17-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. Though it disagrees with FDA, iForce Nutrition has agreed to the recall because it had already ceased selling the product. This recall does not include iForce Nutrition's Reversitol V2, which contains 84 capsules and does not contain 6-Etioallochol-1,4-Diene-3,17-Dione (ATD).

FDA has requested that iForce Nutrition 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. iForce Nutrition has not received any adverse event reports nor are they aware of any adverse events associated with the use of these products.

Reversitol had been sold nationwide, both in retail stores and direct to consumers, but was discontinued by iForce Nutrition on December 10, 2009. The product was sold in red bottles with a white cap, containing sixty (60) capsules and was Manufactured for Distribution by Tribravus Enterprises, LLC. Although this product was discontinued nearly a year ago, it has come to the attention of iForce Nutrition that some online retailers may still have remaining inventory that they are offering for sale.

Consumers who have Reversitol in their possession should stop using it immediately. If consumers experience any adverse side effects due to consumption of this product, they should contact a physician right away. Adverse reactions or quality problems experienced with the use of this product may be reported to iForce Nutrition or 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, preaddressed 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 Reversitol to return any unused portion to the retail location from which it was purchased or if purchased directly from iForce Nutrition to return any unused portion to: iForce Nutrition, 1305 Hot Spring Way #103, Vista CA 92081; Attention: Reversitol Recall. Please note that this recall does not include iForce Nutrition's Reversitol V2, which contains 84 capsules and does not contain 6-Etioallochol-1,4-Diene-3,17-Dione (ATD).

Consumers with questions regarding this recall can contact the company at 1-877-743-6460 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).

Photos: Product Labels[11]