Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

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

DATE: January 3, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Drive Total Energy Recall

SUGGESTED ACTION: **Unclassified Recall; Rock Hard Extreme and Passion Coffee Dietary Supplement's lab analyses found that the products to contain Sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used in the treatment of male Erectile Dysfunction (ED), making these products unapproved new drugs; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. Rock Hard Extreme and Passion Coffee, distributed by Drive Total Energy, are sold on internet sites, online marketplaces, and in retail outlets in single blister packs, single packets, and 10-count capsule bottles. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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.

Drive Total Energy Issues a Voluntary Recall of Rock Hard Extreme and Passion Coffee Dietary Supplements

Company Contact:
Drive Total Energy
1-619-825-9422
Monday through Friday from 9:00 am – 5:00 pm PST

FOR IMMEDIATE RELEASE - December 30, 2010 – San Diego, CA - Drive Total Energy announced today it is voluntarily recalling the company's Rock Hard Extreme and Passion Coffee Dietary Supplements. Drive Total Energy is conducting the voluntary recall after being informed by the Food and Drug Administration (FDA) that lab analyses found that the products to contain Sulfoaildenafil, an analogue of Sildenafil, an FDA-approved drug used in the treatment of male Erectile Dysfunction (ED), making these products unapproved new drugs. The active drug ingredient is not listed on the product label.

The undeclared ingredient may pose a threat to the consumer because the interaction of the analogue with some prescription drugs (such as nitroglycerin) may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take other prescription drugs. Erectile Dysfunction is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

To date, Drive Total Energy is not aware of any reports made to the FDA concerning any adverse effects associated with the use of Rock Hard Extreme or Passion Coffee. In addition, Drive Total Energy currently has not received any complaints from our customers. Out of an abundance of caution and concern for the health and welfare of our customers, Drive Total Energy is voluntarily notifying our customers of the FDA's findings.

Drive Total Energy takes this recall very seriously and recommits to the diligent work required in ensuring its products remain free of any potentially unapproved chemicals. We take the utmost pride in our products' quality control without compromising our customer's health.

Rock Hard Extreme and Passion Coffee, distributed by Drive Total Energy, are sold on internet sites, online marketplaces, and in retail outlets in single blister packs, single packets, and 10-count capsule bottles Rock Hard Extreme single pack Lot # 1152010, expiration date Jan. 15, 2013; Rock Hard Extreme Bottle Lot # 1152010, expiration date Jan. 15, 2013; Passion Coffee UPC 7 97882 00001 2.

We urge consumers who have purchased these products to discontinue their use and return the products to their place of purchase for a full refund. Customers with questions can call Drive Total Energy at 1-619-825-9422 Pacific Coast Time Monday through Friday from 9:00 am – 5:00 pm PST for instructions on the return and refund process. It is the position Drive Total Energy that we did not in any way knowingly or intentionally violate the law with regard to the distribution of these products.

Adverse reaction 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]. Mail to address on the pre-addressed form. Fax: 1-800-FDA-0178.

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