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: August 31, 2012

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

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

SUBJECT: Brand New Energy Recall

SUGGESTED

ACTION: **Unclassified Recall; All lot codes of EphBurn 25, because one lot of EphBurn 25 was sampled by the FDA and found to contain ephedrine alkaloids, making it an unapproved drug; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product may have been distributed in the State of Indiana. The product subject to recall, EphBurn 25, was distributed to various retail stores nationwide, and the product was sold via the Internet from the period of time of approximately April 2010 through August 2012. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Brand New Energy Announces Voluntary Recall of Dietary Supplement EphBurn 25 Due to Possible Health Risk

Contact:
Consumer:
1-888-234-2595
info@brandnewenergy.com

FOR IMMEDIATE RELEASE - August 30, 2012 - Brand New Energy ("BNE"), dietary supplement re-sale distributor, is recalling all lot codes of EphBurn 25. The recall was initiated on August 28, 2012, after notification by the Food and Drug Administration (FDA) to a third-party retailer which purchased EphBurn 25 that one lot of EphBurn 25 was sampled by the FDA and found to contain ephedrine alkaloids, making it an unapproved drug.

Ephedrine is commonly used as a stimulant, appetite suppressant, concentration aid, and decongestant, and it has been used to help aid in weight loss. The ephedrine alkaloids work mainly by increasing the activity of noradrenaline on adrenergic receptors. A number of adverse effects associated with ephedrine alkaloid-containing dietary supplements have been reported to the FDA. These include elevated blood pressure, rapid heartbeat, nerve damage, muscle injury, and psychosis and memory loss. More serious effects have also been reported, including heart attack, stroke, seizure and death. There have been no reports of adverse events associated with this recalled product.

This recall affects all lot codes and use by dates of EphBurn 25. The product is a 90-count bottle with red capsules and prominently displays the product name "ephBURN 25" in white letters on the front of a red label. There is no UPC code. EphBurn 25 was previously discontinued on or about May of 2012.

BNE is a reseller of nationally-known diet and energy supplements such as Zantrex 3, Trim Spa, Hydroxy Cut and others. The product subject to recall, EphBurn 25, was distributed to various retail stores nationwide, and the product was sold via the Internet from the period of time of approximately April 2010 through August 2012. No other products distributed by BNE are subject to recall.

Consumers who may have purchased EphBurn 25 should immediately discontinue using the product and contact their health care professional if they have experienced any adverse effects. Consumers can contact the distributor of the product at info@brandnewenergy.com or call 1-888-234-2595 (8 a.m. to 4 p.m. PST) to receive further instructions for returning the product or with any questions.

We sincerely regret any inconvenience to consumers. This recall has been taken voluntarily out of concern for the health and safety of consumers.

This recall is being made in cooperation with the US Food and Drug Administration.

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[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2].
  Mail to address on the pre-addressed form.
- Fax: 1-800-FDA-0178

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