Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: May 1, 2014

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Bacai Inc. – RECALL [Drug]

AFFECTED PRODUCT: **LiteFit USA an herbal diet supplement**

SUMMARY: **Unclassified Recall; The recall has been initiated because this product contained sibutramine. Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons.**

The affected LiteFit USA lots include the following lot number 13165, Expires: May 2017.

LiteFit USA was distributed worldwide to wholesalers, retailers, and through the internet.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Bacai by 714-775-0050 from 10:00 am - 6:00 pm PDT.**

****

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.

Bacai Inc. Issues Voluntary Worldwide Recall of LiteFit USA

Contact:
Consumer: 714-775-0050

FOR IMMEDIATE RELEASE - April 29, 2014 - Bacai is voluntarily recalling 13165 lot (lot number is found next to the expiration date) of LiteFit USA, to the retail and consumer level. This product is used as an herbal diet supplement and is packaged in plastic bottles of 30 softgels. Sample analysis by the FDA has revealed that this product contained sibutramine.

Risk Statement: Sibutramine is a controlled substance that was removed from the market in October 2010 for safety reasons. The product poses a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. This product may also interact, in life-threatening ways, with other medications a consumer may be taking.

Bacai is the distributor of LiteFit USA an herbal diet supplement manufactured by Global Herb, LLC. Bacai was approached by Global Herb to distribute its herbal diet supplement LiteFit USA which it guaranteed is made in the US and meets with all US health and safety standards. As proof of its legitimacy, Global Herb provided Bacai with the certification of analysis for LiteFit USA. Based on Global Herb's guaranty and the certification of analysis, in the summer of 2013 Bacai entered into a good faith oral contract to distribute LiteFit USA. Subsequently, Bacai was contacted by the FDA and informed that, unbeknownst to Bacai, LiteFit USA contained Sibutramine.

Without admitting guilt or wrongdoing, Bacai is voluntarily recalling all LiteFit USA distribute by Bacai from June 26, 2013 to March 27, 2014 to the retail and consumer level. Todate, Bacai has not received any reports of adverse events related to this recall.

The affected LiteFit USA lots include the following lot number 13165, Expires: May 2017. LiteFit USA was distributed worldwide to wholesalers, retailers, and through the internet.

Bacai is notifying its distributors and customers by mail and is arranging for return and refunds of all Litefit USA sold in the US. Consumers/distributors/retailers that have product which is being recalled should stop using and return it to the place of purchase.

Consumers with questions regarding this recall can contact Bacai by 714-775-0050 from 10:00 am - 6:00 pm PDT. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

###