Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: December 26, 2013

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

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

SUBJECT: Deseo Rebajar, Inc [Drug]

AFFECTED PRODUCT: **Burn 7 Capsules a dietary supplement Lot #MFD: 07.18.2013 (Exp: 07.17.2015).**

SUMMARY: **Unclassified Recall; Found to contain undeclared Sibutramine.**

The products were sold online on the website www.deseorebajar.com.

ACTION: **For consumer inquiry only. Consumers with questions should contact Deseo Rebajar Inc. at 787.961.6464 or via e-mail at sales@adipotrim.com Monday - Friday, 8:00 am - 5:00 pm, [GMT time zone].**

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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.

Deseo Rebajar Inc. Issues Voluntary Recall of Burn 7 Capsules Due to Undeclared Active Ingredient

Contact
Consumer:
787-961-6464

FOR IMMEDIATE RELEASE - December 23, 2013 - Deseo Rebajar Inc., is voluntarily recalling **lot #MFD: 07.18.2013 (Exp: 07.17.2015) of Burn 7 Capsules** to the consumer level. The FDA laboratory analysis of this dietary supplement found the **Burn 7 Capsules** product to contain undeclared Sibutramine. Sibutramine was a previously approved controlled substance for the treatment of obesity that was removed from the

U.S. market in October 2010 for safety reasons, making this product an unapproved new drug. Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk to patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. Sibutramine has been withdrawn from U.S marketplace. The active drug ingredient is not listed on the label for these products. The recalled products are packaged in 30-count plastic bottles labeled with lot number **#MFD: 07.18.2013**.

The product lot was sold directly to individual customers in our offices in Fajardo, Caguas and Bayamon and in website www.deseorebajar.com. We sincerely regret any inconvenience to our customers.

Consumers with questions should contact Deseo Rebajar Inc. at 787.961.6464 or via e-mail at sales@adipotrim.com Monday - Friday, 8:00 am - 5:00 pm, [GMT time zone]. 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 events that may be related to the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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

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

Deseo Rebajar Inc. is taking this voluntary action because it is committed to the health and safety of its customers and to the quality of its select brands. We are working diligently to make available appropriate natural herbal regulations. We are moving forward with new custom formula. We value our relationship with you and will continue to provide you with the best

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