Indiana State Department of Health
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Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 16, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Inaffit, LLC - RECALL [Drug]

AFFECTED PRODUCT: Natureal light green and dark green capsules

SUMMARY: **Unclassified Recall; The product is being recalled because FDA laboratory testing found Natureal to contain sibutramine. This undeclared ingredient makes this product an unapproved new drug for which safety and efficacy have not been established.**

The product is used as a weight loss dietary supplement and is packaged in clear bottle with light green and dark green capsules. The affected Natureal product includes lots Manufactured 3/12/2015 Expiration Date 3/11/2017.

The recalled product was distributed nationwide via the internet.

SUGGESTED ACTION: **For consumer inquiry only. Consumers with questions regarding this recall can contact Inaffit, LLC by email at returns@naturealfls.com.**

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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.

Inaffit, LLC Issues Voluntary Nationwide Recall of Natureal Due to Undeclared Sibutramine

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.

For Immediate Release

November 9, 2015

Contact

Consumers

Inaffit, LLC
returns@naturealfls.com

Media

Tiffani Smith
(301) 538-9682

Firm Press Release
View Product Photos

Bethesda, MD - Inaffit, LLC is voluntarily recalling all lots of Natureal light green and dark green capsules to the consumer level after FDA laboratory testing found Natureal to contain sibutramine.

Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010. 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 undeclared ingredient makes this product an unapproved new drug for which safety and efficacy have not been established. This product may also interact in life-threatening ways with other medications a consumer may be taking.

The product is used as a weight loss dietary supplement and is packaged in clear bottle with light green and dark green capsules. The affected Natureal product includes lots Manufactured 3/12/2015 Expiration Date 3/11/2017 which have been distributed from the Natureal office, 14707 South Dixie Highway, Suite 213, Palmetto Bay, FL 33176 and nationwide to consumers via internet www.naturealfls.com.

Inaffit, LLC is notifying its customers by Email and is arranging for return. Consumers who are currently in possession of recalled Natureal light green and dark green capsules should stop using the product and discard. Inaffit, LLC switched to a U.S. Food and Drug Administration Registered Facility to manufacture their dietary supplements and changed the Natureal packaging to a clear bottle with clear capsules.

Consumers with questions regarding this recall can contact Inaffit, LLC by email at returns@naturealfls.com. 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 voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

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Product Photos