



**Indiana State
Department of Health**
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 28, 2014

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

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

SUBJECT: GlaxoSmithKline (GSK) Consumer Healthcare - RECALL [Drug]

**AFFECTED
PRODUCT:** alli® weight loss products

SUMMARY: Unclassified Recall; The recall has been initiated because the company believes that some packages of the product were tampered with and may contain product that is not authentic alli®.

All alli® weight loss products are being RECALLED - Nationwide.

alli® is a turquoise blue capsule with a dark blue band imprinted with the text "60 Orlistat". It is packaged in a labeled bottle that has an inner foil seal imprinted with the words: "Sealed for Your Protection." Consumers should confirm any alli® in their possession matches this description. A range of tablets and capsules of various shapes and colors were reported to be found inside bottles. Additionally, some bottles inside the outer carton were missing labels and had tamper-evident seals that were not authentic. These tampered products were purchased in retail stores.

**SUGGESTED
ACTION:** Recommend notification of affected parties via phone, fax, or e-mail. Consumers who have product they are unsure or concerned about should not use it. Instead, they should call GSK promptly at 800-671-2554, and a representative will provide further instructions. Furthermore, if any recalled products are found, notify this office at 317-233-8475.

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.



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To promote and provide
essential public health services.

Glaxosmithkline Recalls Alli®

Contact:

Consumer:
800-671-2554

Media:

Deborah Bolding
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412-327-5540

FOR IMMEDIATE RELEASE - March 27, 2014 - GlaxoSmithKline (GSK) Consumer Healthcare is voluntarily recalling all alli® weight loss products from U.S. and Puerto Rico retailers as the company believes that some packages of the product were tampered with and may contain product that is not authentic alli®. GSK is conducting an investigation and is working with the knowledge of the U.S. Food and Drug Administration (FDA) on this retailer level recall.

GSK received inquiries from consumers in seven states about bottles of alli® that contained tablets and capsules that were not alli®. A range of tablets and capsules of various shapes and colors were reported to be found inside bottles. Additionally, some bottles inside the outer carton were missing labels and had tamper-evident seals that were not authentic. These tampered products were purchased in retail stores.

"Safety is our first priority and we are asking retailers and pharmacies to remove all alli from their shelves immediately," said Colin Mackenzie, President Consumer Healthcare North America. "We have posted a Consumer Alert on our website, www.myalli.com, and issued a News Release with information and photographs to help consumers determine if their alli is authentic."

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Consumers who have product they are unsure or concerned about should not use it. Instead, they should call GSK promptly at 800-671-2554, and a representative will provide further instructions. If they have consumed questionable product, they should also contact their healthcare providers.

"We are committed to finding out what happened and to doing everything possible to prevent future issues with alli®," said Mackenzie. "We regret any inconvenience caused by this retailer recall."

Media contact: Deborah Bolding (deborah.g.bolding@gsk.com) (412-327-5540)

About alli® alli®

(60 mg orlistat capsules) is the only FDA approved over-the-counter weight loss aid clinically proven to help boost weight loss efforts. alli® is for weight loss in overweight adults, 18 years and older when used along with a reduced-calorie and low fat diet.

About GlaxoSmithKline

Consumer Healthcare GlaxoSmithKline Consumer Healthcare is one of the world's largest over-the-counter consumer healthcare products companies. Its well-known brands include Nicorette® and NicoDerm® CQ, the leading smoking cessation products; alli®, the only FDA-OTC weight loss aid; as well as medicine cabinet staples, Aquafresh®, Sensodyne®, Tums®, and Breathe Right®, all of which are trademarks owned by and/or licensed to GSK Group of Companies.

About GlaxoSmithKline

GlaxoSmithKline -- one of the world's leading research-based pharmaceutical and healthcare companies -- is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information visit: <http://www.gsk.com>.

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