Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: August 7, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer
W. Alan Hamlin, Sup. Southern District

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

SUBJECT: Health and Beyond LLC Recall [Drug]

SUGGESTED ACTION: **Unclassified Recall; Quantity lots of product Tranquility because the products have been found to contain a trace of Doxepin which is a pharmaceutical for sleep and Chlorpormazine for psychotic disorders; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. The product was distributed Nationwide, wholesale, retail and via internet. Detail store information is not available at this time. In addition, if any recalled products are found, please 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.

Health and Beyond LLC Issues Voluntary Nationwide Recall of Tranquility Product Due to Product Having Traces of Pharmaceutical Ingredients

Contact:
Consumer:
Health and Beyond LLC
561-350-9967
drlarrydirect@gmail.com

FOR IMMEDIATE RELEASE - August 7, 2013 – Boca Raton, FL, Health and Beyond LLC is voluntarily recalling quantity lots of product Tranquility. The products have been found to contain a trace of Doxepin which is a pharmaceutical for sleep and Chlorpormazine for psychotic disorders.

The product potentially could result in dizziness and cause public health risk. Health and Beyond LLC has not received any reports of adverse events related to this recall.

The product is used as a sleep product and is packaged in a white bottle with 30 pills per bottle with lot # 36678 and 36680.

The affected product in the Tranquility lots include the following expiration date 9/15.

The product was distributed Nationwide, wholesale, retail and via internet.

Health and Beyond LLC is notifying its distributors and customers by personal phone call and written recall letter and is arranging for return/replacement etc. of all recalled products. Consumers/distributors/retailers that have product which is being recalled should stop using and return product to place of purchase if you choose.

Consumers with questions regarding this recall can contact Health and Beyond LLC via the e-mail address drlarrydirect@gmail.com on days of the week from Monday -Friday. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this 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.

- **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

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

###

RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]