Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

**DATE:** December 27, 2010

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

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

**SUBJECT:** RockHard Laboratories Recall

**SUGGESTED ACTION:** **Unclassified Recall; Dietary supplements sold under the brand names RockHard Weekend and Pandora contain an analogue of Sildenafil. Sildenafil is an FDA-approved drug used as treatment for male Erectile Dysfunction (ED); Recommend notification of affected stores via phone, fax or e-mail.**

**From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. The active drug ingredient is not listed on the label for these products. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.**

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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.

## RockHard Laboratories Issues a Voluntary Recall of Specific Lots of the Dietary Supplements RockHard Weekend and Pandora

**Contact:**
Customer Service
877-576-9363

**FOR IMMEDIATE RELEASE** - December 22, 2010 - RockHard Laboratories announced today that it is conducting a voluntary nationwide recall of the company's dietary supplements sold under the brand names RockHard Weekend and Pandora specific to the following Lot Numbers:

- RockHard Weekend Lot Numbers: 100159 and 100260 sold as blister packs, 3ct bottles and 8ct bottles.
- Pandora Lot Numbers: 100378 sold as blister packs.

RockHard Laboratories is conducting a voluntary recall after its independent testing found the RockHard Weekend and Pandora products, specific to the above lot numbers, contain an analogue of Sildenafil. Sildenafil is an FDA-approved drug used as treatment for male Erectile Dysfunction (ED). The active drug ingredient is not listed on the label for these products.

Use of these products may pose a threat to consumers because the analogue may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

RockHard Laboratories advises any customers in possession of the RockHard Weekend and/or Pandora products matching the lot numbers above to return any unused product for a full refund to the company directly. Customers can call 1.877.576.9363 for instructions on the return and refund process.

RockHard Laboratories is committed to improving its products and avoiding future recall issues by sourcing higher quality raw ingredients and expanding testing. RockHard Laboratories promises its customers the highest possible quality and welcomes the recall process as further evidence of our commitment to our brands, products and consumers.

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

- Online: http://www.fda.gov/MedWatch/report.htm[9]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[10]. 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.