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: May 2, 2011

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

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

SUBJECT: Ethos Environmental, Inc. Expanded Recall

SUGGESTED ACTION: **Unclassified Recall; Dietary supplement sold under the brand name Regenerect because FDA lab analysis has confirmed the presence of Sulfoaildenafil, an analogue of Sildenafil, making these products unapproved new drugs; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. RAW Organic Food Bar lots mentioned below were distributed nationally in USA. The product reached consumers through retail stores, mail order, direct delivery etc. 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.

Ethos Environmental, Inc. Issues a Voluntary Recall of Specific Lots Of The Dietary Supplement Regenerect

Contact:
Customer Service
(866) 925-9553

FOR IMMEDIATE RELEASE - April 28, 2011 – Ethos Environmental, Inc. announced today that it is conducting a voluntary nationwide recall of the company's dietary supplement sold under the brand name Regenerect with the following Lot Numbers:

Regenerect Lot Numbers:
100521 - blue capsule sold individually in foil packets, expires 5/2012
112850 - clear capsule sold individually in foil packets, expires 11/2013

Ethos Environmental, Inc. is conducting a voluntary recall because FDA lab analysis has confirmed the presence of Sulfoaildenafil, an analogue of Sildenafil, making these products unapproved new drugs. 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.

According to the FDA, 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. FDA has advised that consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. FDA has advised that ED is a common problem in men with these conditions, and consumers may seek these types of products to enhance sexual performance.

Ethos Environmental, Inc. has distributed Regenerect via sales made over the internet to consumers in the United States of America and Puerto Rico.

Ethos Environmental, Inc. advises any customers in possession of the Regenerect product matching the lot numbers above to return any unused product for an exchange, or a full refund, to the company directly. Customers can call (866) 925-9553 (Monday through Friday from 6am to 6pm Pacific Time) for instructions on the return and exchange/refund process.

Ethos Environmental, Inc. is committed to improving its products and avoiding future recall issues by improving testing procedures. Ethos Environmental, in an effort to be abundantly cautious, is issuing a voluntary recall on the two lots, mentioned above, that did not comply with the newly adopted testing protocol of Ethos Environmental. The Company's testing protocol and test results will be available on the Company's website for all consumers. Any consumers requesting an exchange of product from the two lots in question will be receiving Regenerect product that has been subjected to the Company's new testing procedures. Ethos Environmental 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[1]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: http://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.

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