Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: March 12, 2013

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

DCB

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

SUBJECT: Green Planet, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; A product sold as a dietary supplement under the brand name of "Night Bullet," found to contain trace amounts of an analogue of an FDA-approved drug; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product was distributed in the State of Indiana. Night Bullet was sold nationwide between October 2012 and March 2013 to wholesalers and sample provided at trade shows. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Green Planet, Inc. Issues a Voluntary Nationwide Recall of One Lot of "Night Bullet," a Product Marketed as a Dietary Supplement to Support Male Sexual Performance, Due to Undeclared, Potentially Hazardous Active Ingredient

Contact:
Consumer:
877-621-2048
contact@thegreenplanetproducts.com

FOR IMMEDIATE RELEASE - March 11, 2013 - Green Planet, Inc. is conducting a voluntary consumer recall of a product sold as a dietary supplement under the brand name of "Night Bullet," found to contain trace amounts of an analogue of an FDA-approved drug.

Finished product of Night Bullet was tested and found to contain trace amounts of an analogue of an FDA-approved drug. Analytical tests conducted by the Food and Drug Administration (FDA) of Night Bullet found that the product contains trace amounts of Sulfohydroxyhomosildenafil and Aminotadalafil. Sulfohydroxyhomosildenafil and Aminotadalafil are an analogues of sildenafil. Sildenafil is the active pharmaceutical ingredient in an FDA-approved drug that is used to treat erectile dysfunction (ED) making this product an unapproved drug.

These undeclared active ingredients pose a threat to consumers because sildenafil may interact with nitrates found in some prescription drugs (such as nitroglycerin) and 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 they may seek products to enhance sexual performance. Additionally sildenafil may cause side effects such as, headaches and flushing. Green Planet has not received any reports of adverse events related to this recall.

Night Bullet is marketed as a supplement for male enhancement. The recalled products are in capsule form, packaged in one (1) count blister packs. The lot and expiration date can be found on the back of the package. The following lot is being recalled:

Product	Batch Lot #	UPC Code	EXPIRATION DATES
Night Bullet	B43N032	018505122233	10/2015

Night Bullet was sold nationwide between October 2012 and March 2013 to wholesalers and sample provided at trade shows.

Green Planet is notifying its wholesalers through written correspondence. We urge consumers who have purchased these products to immediately discontinue their use and contact their physician if they have experienced any problems that may be related to taking this product. The Company is advising consumers to return the product to their place of purchase. Consumers may also return products directly to Freedom Trading. Customers can call the Company at 877-621-2048 Monday through Friday from 9:00 am – 5:00 pm PST for instructions on the return and refund process.

Any adverse events 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: 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 preaddressed form.
- Fax: 1-800-FDA-0178

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

Photo: Product Labels[5]