## **U.S. Food and Drug Administration**

Protecting and Promoting Your Health

## Public Notification: Happy Passengers contains hidden drug ingredient

[1-21-2015] The Food and Drug Administration (FDA) is advising consumers not to purchase or use Happy Passengers, a product promoted and sold for sexual enhancement on various websites and in retail stores.

FDA laboratory analysis confirmed that Happy Passengers contains sildenafil, the active ingredient in the FDA approved prescription drug Viagra, used to treat erectile dysfunction (ED). This undeclared ingredient may interact with nitrates found in some prescription drugs such as nitroglycerin and may lower blood pressure to dangerous levels. Men with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates.

Health care professionals and patients are encouraged to report adverse events or side effects related to the use of this product to FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at <u>MedWatch Online Voluntary Reporting Form</u> (<a href="https://www.accessdata.fda.gov/scripts/medwatch/">https://www.accessdata.fda.gov/scripts/medwatch/</a>), or;
- Download and complete the <u>form</u>
   (<a href="http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.p">http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.p</a>

   df), then submit it via fax at 1-800-FDA-0178.

Note: This notification is to inform the public of a growing trend of dietary supplements or conventional foods with hidden drugs and chemicals. These products are typically promoted for sexual enhancement, weight loss, and body building and are often represented as being "all natural." FDA is unable to test and identify all products marketed as dietary supplements that

have potentially harmful hidden ingredients. Consumers should exercise caution before purchasing any product in the above categories.

For more information:

- <u>Tainted Sexual Enhancement Products</u>
   (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234539.htm)
- <u>Subscribe to the RSS feed</u>
   (http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/TDS/rss.xml)
- <u>Beware of Fraudulent 'Dietary Supplements'</u> (/ForConsumers/ConsumerUpdates/ucm246744.htm)

## **Contact FDA**

Toll Free

(855) 543-3784, or

(301) 796-3400

druginfo@fda.hhs.gov (mailto:druginfo@fda.hhs.gov)

## **Human Drug Information**

**Division of Drug Information** 

(http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm082585)
(CDER)

Office of Communications

Feedback Form (http://www.accessdata.fda.gov/scripts/email/cder/comment.cfm)

10001 New Hampshire Avenue

Hillandale Building, 4th Floor

Silver Spring, MD 20993