Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Caverflo.com Issues Voluntary Nationwide Recall of Caverflo Natural Herbal Coffee due to the Presence of Undeclared Active Pharmaceutical Ingredients and Undeclared Milk

For Immediate Release

May 25, 2017

Contact

Consumers

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Media

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Announcement

Caverflo.com is voluntarily recalling all lots of Caverflo Natural Herbal Coffee, 25 grams to the consumer level. FDA laboratory analysis confirmed the presence of Sildenafil and Tadalafil which are the active ingredients in two FDA-approved prescription drugs used for the treatment of erectile dysfunction (ED). Caverflo.com has received a report of an individual death after use of the coffee. Caverflo Natural Herbal Coffee may also contain undeclared milk.

These undeclared ingredients 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. People who have an allergy or severe sensitivity to milk run the risk of serious or life threatening allergic reaction if they consume this product.

Caverflo Natural Herbal Coffee is used as a male enhancement and is packaged in 25 gram black foil packs, UPC 9555671709994. Caverflo.com distributed this product from August 2016 through February 2017. Caverflo Natural Herbal Coffee is consumed as an instant coffee. Caverflo Natural Herbal Coffee was distributed nationwide to consumers via internet at Caverflo.com.

Caverflo.com is notifying its customers by email. Consumers that have Caverflo Natural Herbal Coffee which is

being recalled should stop using/discard/ and contact their doctor.

Consumers with questions regarding this recall can contact Caverflo.com at 214-803-4652 or **coffeekingb@yahoo.com (mailto:coffeekingb@yahoo.com)** Monday thru Friday 9am to 5pm CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug 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.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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

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