

Mike DeWine
Governor**Jon Husted**
Lieutenant Governor**Dorothy Pelanda**
ODA Director**Amy Acton, MD**
ODH Director

DATE: April 5, 2019

TO: Health Commissioners, Directors of Environmental Health and Interested Parties

RE: Recall Announcement (ODA/ODH) 2019-063

Brian Richardson DBA "In Tha Pink" Issues Voluntary Nationwide Recall of Kopi Jantan Tradisional Natural Herbs Coffee Due to Presence of Undeclared Sildenafil and Tadalafil

Brian Richardson DBA "In Tha Pink", is voluntarily recalling lots with the expiration of October 13, 2020 (13/10/2020) of ground Kopi Jantan Tradisional Natural Herbs Coffee to the consumer level. FDA analysis has found the product to be tainted with Sildenafil and Tadalafil. Sildenafil and tadalafil are FDA approved drugs for the treatment of male erectile dysfunction. The presence of these undeclared active ingredients renders the product an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Consumption of a product with undeclared sildenafil and tadalafil may pose a threat to consumers because these active ingredients may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels which can be life threatening. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates and may be the population most likely to be affected. To date, "In Tha Pink" has not received any reports of adverse events related to this recall.

The product is marketed as a dietary supplement for sexual enhancement and sold in individual 13 gram packages, UPC 9 557205 06008 3 with an expiration date of October 13, 2020 (13/10/2020) stamped on the back of the package. The recalled Kopi Jantan Tradisional Natural Herbs Coffee was distributed nationwide in the USA by online retail sites, including but not limited to Ebay and through mail orders, since September, 2017.

Brian Richardson DBA "In Tha Pink" is notifying its customers by mail and arranging for return of all recall products.

Consumers or retailers that have the product which is being recalled should stop using and return the product to "In Tha Pink" for a full refund.

Consumers with questions regarding the recall can contact "In Tha Pink" by phone (214) 803-4652, Monday through Friday, 9 a.m. to 4 p.m., Central Daylight Time. 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 associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form 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.