

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

DATE: May 7, 2019

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

RE: Recall Announcement (ODA/ODH) 2019-074

STIFF BOY LLC. Issues Voluntary Nationwide Recall of THE BEAST Capsules Due to Presence of Undeclared Sildenafil

STIFF BOY LLC. is voluntarily recalling all lots within expiry of The Beast capsules to the consumer level. FDA analysis has found the product to be tainted with sildenafil. Sildenafil is an FDA approved drug for the treatment of male erectile dysfunction and is in a class of drugs called phosphodiesterase (PDE-5) inhibitors.

The presence of sildenafil in THE BEAST Capsules renders it an unapproved drug for which safety and efficacy have not been established and, therefore, subject to recall.

Consumption of a product with undeclared PDE-5 inhibitors may pose a threat to consumers because the 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, STIFF BOY LLC. has not received any reports of adverse events related to this recall.

The product is marketed as a dietary supplement for male enhancement and is packaged in blue wrapping and blue box with an image of a beast, 4 capsules per package with no UPC barcode. All lots within expiry are being recalled. Product was distributed nationwide in the USA to online customers.

STIFF BOY LLC is notifying its customers by email and is arranging for return of all recalled products.

Consumers that have product which is being recalled should stop using it immediately and return to the place of purchase.

Consumers with questions regarding this recall can contact STIFF BOY LLC by calling (914)281-4059 or e-mail info@youcanbeabeast.com 7 days of the week from 9am and 5pm, Eastern Standard Time, for instructions on the disposition process.

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](#)
- Regular Mail or Fax: [Download form](#) 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.

Company Contact Information**Consumers:**

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