



# Public Notification: Big N Hard Contains Hidden Drug Ingredient

[5-3-2017] The Food and Drug Administration (FDA) is advising consumers not to purchase or use Big N Hard, a product promoted for sexual enhancement.

FDA laboratory analysis confirmed that Big N Hard contains tadalafil, the active ingredient in Cialis, an FDA-approved prescription drug for 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 the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at [MedWatch Online Voluntary Reporting Form \(https://www.accessdata.fda.gov/scripts/medwatch/\)](https://www.accessdata.fda.gov/scripts/medwatch/), or;
- Download and complete the [form \(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf\)](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM349464.pdf), 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.

Please refer to the links below for more information:

