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Governor

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State Health Commissioner

**Indiana State
Department of Health**
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DATE: November 5, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: FDA Warns Consumers on Sexual Enhancement Products

SUGGESTED

ACTION: FDA Advisory; Warning consumers that Stiff Nights, a product marketed as a dietary supplement for sexual enhancement, contains an ingredient that can dangerously lower blood pressure and is illegal; Provided in case of consumer inquiry.

FDA NEWS RELEASE

For Immediate Release: Nov. 5, 2009
Media Inquiries: Christopher Kelly, 301-796-4676, christopher.kelly@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Warns Consumers on Sexual Enhancement Products

Another dietary supplement is found to be contaminated with potentially dangerous ingredient

The U.S. Food and Drug Administration is warning consumers that Stiff Nights, a product marketed as a dietary supplement for sexual enhancement, contains an ingredient that can dangerously lower blood pressure and is illegal.

Over the past several years, the FDA has found **many products** marketed as "dietary supplements" for sexual enhancement that contain undeclared active ingredients of FDA-approved drugs, analogs of approved drugs and other compounds that do not qualify as "dietary ingredients." The FDA has issued multiple alerts about these contaminated dietary supplements.

Consumers and health care professionals should be aware of this problem and the health hazard it presents. Sexual enhancement products that claim to work as well as prescription products are likely to contain a contaminant. Use of such products exposes consumers to unpredictable risk and the potential for injury or even death.

In the case of Stiff Nights, following a consumer complaint, the FDA determined that the product contains sulfoildenafil. This is a chemical similar to sildenafil, the active ingredient in Viagra. Sulfoildenafil may interact with prescription drugs known as nitrates, including nitroglycerin, and cause dangerously low blood pressure.

The product is distributed on Internet sites and at retail stores by Impulsaria LLC of Grand Rapids, Mich. It is sold in bottles containing 6, 12, or 30 red capsules or in blister packs containing one or two capsules.

"Because this product is labeled as an 'all natural dietary supplement,' consumers may assume it is harmless and poses no health risk," said Deborah M. Autor, director of FDA's Center for Drug Evaluation and Research Office of Compliance. "In fact, this product is illegally marketed and can cause serious complications."

The FDA advises consumers who have experienced any adverse events from sexual enhancement products to consult a health care professional. Consumers and health care professionals should report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/report.htm

The FDA remains committed to stopping the illegal marketing of unapproved drugs and will continue to protect the public with vigorous law enforcement and criminal prosecution of violators.

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