

FDA urges consumers to avoid sexual-enhancement drinks

January 3 2011, By Eryn Brown

The Food and Drug Administration advised consumers on Thursday not to buy or use two drinks sold as supplements for sexual enhancement.

The products, Rock Hard Extreme and Passion Coffee, are sold on websites and possibly in retail outlets, the agency said. Laboratory analysis indicated that both contain sulfoildenafil, an active pharmaceutical ingredient that is similar to sildenafil, the active ingredient in Viagra.

Sulfoildenafil could interact with [prescription medications](#) that include nitrates, the FDA warned, lowering blood pressure to "dangerous levels." Nitrate-containing drugs are often prescribed for men with diabetes, [high blood pressure](#) or heart disease.

The warning arrives barely two weeks after a Dec. 15 sent a warning letter to dietary supplement manufacturers in which the FDA said it would crack down on illegal supplements.

"We want consumers to be aware that there are products masquerading as [dietary supplements](#) that pose significant dangers," FDA Principal Deputy Commissioner Dr. Joshua Sharfstein said at the time.

Sharfstein told reporters that the FDA was concerned primarily with three types of supplements. One class is weight-loss products with active ingredients such as sibutramine, found in the drug Meridia, which was recently withdrawn from the market because of increased risk of heart

attack and stroke. The other two are body-building products that contain [anabolic steroids](#) or "steroid analogs," which can cause [liver injury](#) and increase the risk for heart attack, stroke and death; and sexual-enhancement products such as Rock Hard Extreme and Passion Coffee.

Sharfstein said that the products are poorly labeled, so consumers do not know what they are really buying.

Lawful dietary supplements, according to the FDA, are intended only as "an addition to a standard diet."

"If you have a drug product in it, it's not a supplement," said Judy Blatman, spokeswoman for the Council for Responsible Nutrition, an industry trade organization. "We're extremely supportive of the FDA's actions to warn consumers about products that are masquerading as supplements. ... they're illegal."

Blatman said her organization would like the FDA to get even more aggressive. "We're hoping this will put a chill on companies who are doing this," she said.

In an e-mail to the Los Angeles Times, FDA spokesperson Siobhan DeLancey said that the agency had found nearly 300 such "tainted products" among dietary supplements it has examined. She did not specify how many of those were sexual-enhancement products.

DeLancey also said that the FDA had received reports of fatalities in people using illegal sexual-enhancement products.

The FDA advised consumers to stop using Rock Hard Extreme and Passion Coffee immediately, and to throw them away. It encouraged people who had experienced side effects from either drink to notify their doctor.

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