



THE FOOD AND DRUG ADMINISTRATION / AN AGENCY OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FDA WARNS CONSUMERS ABOUT DANGEROUS INGREDIENTS IN “DIETARY SUPPLEMENTS” PROMOTED FOR SEXUAL ENHANCEMENT

The U.S. Food and Drug Administration (FDA) is warning consumers not to purchase or consume Zimaxx, Libidus, Neophase, Nasutra, Vigor-25, Actra-Rx, or 4EVERON. These products are promoted and sold on web sites as “dietary supplements” for treating erectile dysfunction (ED) and enhancing sexual performance, but they are in fact illegal drugs that contain potentially harmful undeclared ingredients. These products have not been approved by FDA, and there is no guarantee of their safety and effectiveness, or of the purity of their ingredients.

FDA advises consumers who have used any of these products to discontinue use and to consult their health care provider. FDA encourages anyone experiencing ED to seek guidance from a health care provider before purchasing a product to treat this medical condition.

“These products threaten the public health because they contain undeclared chemicals that are similar or identical to the active ingredients used in several FDA-approved prescription drug products. This risk is even more serious because consumers may not know that these ingredients can interact with medications and dangerously lower their blood pressure,” said Dr. Steven Galson, Director of FDA’s Center for Drug Evaluation and Research.

Chemical analysis by FDA revealed that Zimaxx contains sildenafil, which is the active pharmaceutical ingredient in Viagra, a prescription drug approved in the United States to treat ED. The other products contain chemical ingredients that are analogues of either sildenafil or a pharmaceutical ingredient called vardenafil. Vardenafil is the active ingredient in Levitra, a prescription drug that, like Viagra, is approved in the United States to treat ED. There is no mention of any of these ingredients in any of the illegal products’ labeling.

This deception poses a threat to consumers because the undeclared ingredients may interact with nitrates found in some prescription drugs (such as nitroglycerin) and lower blood pressure to dangerous levels. Consumers with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. ED is a common problem in men with these conditions, and they may seek products like the ones noted above because these products claim that they are “all natural” or that they do not contain the active ingredients used in FDA-approved ED drugs. In addition, because the manufacturing source of the active ingredients in these “dietary supplements” is unknown, there is no assurance that the ingredients are safe, effective, or pure.

FDA Warning Letters to the firms marketing these products state that the products are illegal drugs based on claims made for the products or their ingredients. The letters also state that the products’ labeling is false and misleading because it fails to disclose the presence of the chemical ingredients or the potential side-effects associated with the products’ consumption. FDA instructed agency staff to stop the importation of Libidus, and the agency recently stopped

a shipment of 4 EVERON from entering the United States. Based on responses to these actions, FDA may take additional enforcement steps.

Today's actions follow a first-of-its-kind FDA survey, in which the agency analyzed 17 dietary supplements marketed on the internet to treat ED and to enhance sexual performance in men. "Our survey found that many of the so-called 'dietary supplements' marketed as treatments for erectile dysfunction actually contain non-dietary chemicals, including chemicals used as active ingredients in FDA-approved drugs. The claims made for these products were in fact claims made for the undeclared non-dietary chemicals they contain, which rendered them illegal drugs. FDA is committed to protecting the public health by removing such illegal and dangerous products from the market," said Margaret O'K. Glavin, FDA's Associate Commissioner for Regulatory Affairs.

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