



14 November 2013

FDA ADVISORY
No. 2013-052

SUBJECT: CONSUMER HEALTH WARNING ON OxyElite Pro™ Capsule and Powder FOOD/DIETARY SUPPLEMENTS LINKED TO LIVER DISEASES



Food/dietary supplement OxyElite Pro™, manufactured by US Plabs LLC in Dallas, Texas, USA, with claim as a product for weight loss is now the subject of recall by the U.S. Food and Drug Administration (USFDA). The product is not registered in the Philippines.

OxyElite Pro™ has been linked to liver diseases and there is a reasonable probability that the product is adulterated. The following variances are being recalled:

- **OxyElite Pro Super Thermo Capsules**
- **OxyElite Pro Ultra-Intense Thermo Capsules**
- **OxyElite Pro Super Thermo Powder**

On 6 November 2013, the US FDA notified US Plabs about the findings that showed a link between the use of OxyElite Pro products and a number of patients suffering from liver diseases. The US FDA also noted that cases of liver damage after using OxyElite Pro products have been found in a number of other States. According to the FDA News Release dated 10 November 2013, a review of 46 medical records of patients submitted by Hawaii Department of Health to US FDA, 27 had taken dietary supplements labeled as OxyElite Pro before becoming ill. Seventeen (17) of the 27 patients reported that OxyElite Pro was the only supplement they were taking. One death occurred. One patient has already required liver transplantation. A number of patients are still awaiting liver transplant.

US FDA Deputy Commissioner for Foods and Veterinary Medicine Michael R. Taylor said that the product recall was undertaken to ensure that adulterated and harmful products do not reach the American public. Aegeline, a new food/dietary supplement ingredient extracted from bael plant (*Aegle marmelos*) which was never marketed in the U.S. before 15 October 1994, is now under scrutiny as a possible adulterant of OxyElite Pro capsules and powder. Aegeline may appear on a product label as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide. No food/dietary supplement containing aegeline is registered in the Philippines.





Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



All consumers are advised to exercise utmost caution - stop buying OxyElite Pro over the internet or other food/dietary supplements that are unregistered. Consumers should always consult their doctors before undergoing significant weight reduction and taking any food/dietary supplements.

All manufacturers and distributors are ordered to secure FDA License to Operate and to register all their food/dietary supplements with the FDA.

All field Food and Drug Regulation Officers are ordered to coordinate with the local government units to ensure that OxyElite Pro products, among other unregistered health products, are not sold, offered for sale or use in outlets. The Bureau of Customs is likewise requested to continue their vigilance in guarding the national border against the entry of toxic food and drug products.

To report any adverse reaction, kindly email us at report@fda.gov.ph or log in at our FDA website (www.fda.gov.ph) and use the eReport platform. For more information or clarification, please email us via info@fda.gov.ph.


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