بسم الله الرحمن الرحيم

މޯލްޑިވްސް ފުޑް އެންޑް ޑްރަގް އޮތޯރިޓީ

މިނިސްޓްރީ އޮފް ހެލްތް

މާލެ،

ދިވެހިރާއްޖެ

ނަންބަރު: 182-FPS/FALT/2013/08

ފުޑް އެލާޓް

ހަށިގަނޑު ފަސްކުރުމާއި ބަރުދަން ލުއިކުރުމަށާއި ބޮޑުކުރުމަށް ބޭނުންކުރާ ޑައިޓަރީ ސަޕްލިމެންޓެއް ކަމުގައިވާ އޮކްސީ އިލައިޓް ޕްރޯ އާއި ވަރސާ 1 (OxyELITE Pro and VERSA -1) ބޭނުންކުރުމުން ގިނަ މީހުންނަށް ލިވަރުގެ ހެޕަޓައިޓިސް ޖެހިފައިވާކަމާއި، އެކަމަށް ސަރުކާރުތަކުން ދިރާސާ ސިއްހީ ތަޙުޤީޤުތަކުން، އިންޓަރނޭޝަނަލް ފުޑް ސޭފްޓީ އޮތޯރިޓީސް ނެޓްވޯކް (INFOSAN) ގެ ފަރާތުން މައުލޫމާތު ލިބި އަންގާފައެވެ. އެމެރިކާގެ ސެންޓަރ ފޯ ޑިޒީސް ކޮންޓްރޯލް އެންޑް ޕްރިވެންޝަން އަދި ޔުނައިޓެޑް ސްޓޭޓްސް ފުޑް އެންޑް ޑްރަގް އެޑްމިނިސްޓްރޭޝަން (ޔޫ.އެސް.އެފް.ޑީ.އޭ) އިން މިކަން ދިރާސާ ކުރަމުން ގެންދާކަމަށް ބުނެފައިވެއެވެ. މި ސަޕްލިމެންޓްގައި ހިމެނޭ މާއްދާތަކުގެ ކަމުގައިވާ އެގްލިން (Aegline) އަކީ ކުރީގައި ނަޒަރުކުރެވިފައިނުވާ އާ މާއްދާއެއް ކަމަށްވާތީ، މިކަމުގެ ތަޙުޤީޤު ނިމެންދެން މިޕްރޮޑަކްޓް ބޭނުންނުކުރުމަށް ޔޫ.އެސް.އެފް.ޑީ.އޭ އިން އިލްތިމާސް ކޮށްފައެވެ. މައުލޫމާތު ލިބުނު ގޮތުގައި އުފައްދާ ފަރާތުން އެ ޕްރޮޑަކްޓްތައް ބާޒާރުން ނަގަމުން ގެންދާކަމަށް ބުނެފައިވާއިރު، މި ޕްރޮޑަކްޓް ބޭނުންކުރުމުން ދުރުހެލިވުމަށް ދަންނަވަމެވެ.

މިހެންކަމުން ދިވެހިރާއްޖޭގެ ރައްޔިތުންނަށް މި ޕްރޮޑަކްޓް ބޭނުންކުރުމުގެ އިތުރު ސަލާމަތާއި ގުޅޭގޮތުން ހުށަހަޅާފައިވާ ކަމަށްވާތީ، އޮކްސީ އިލައިޓް ޕްރޯއާއި ވަރސާ 1 (OxyELITE Pro and VERSA -1) އާއި މި ބާވަތުގެ އެހެން އުފެއްދުން ޑައިޓަރީ ސަޕްލިމެންޓްތައް ބޭނުންކުރުމުގައި ވަރަށް ސަމާލުވުން އެދެމެވެ.

ވީމާ، އާއްމު ސިއްޙަތު ރައްކާތެރިކުރުމުގެ ޤާނޫނު ނަންބަރު 7/2012 ގެ 7 ވަނަ ބާބުގެ 43 ވަނަ މާއްދާގެ (ހ) އާއި ހަވާލާދީ މިފަދަ ބާވަތްތަކުގެ އެތެރެކުރުމާއި، ވިއްކުމާއި، ބޭނުންކުރުމަކީ މަނާކަމެއް ކަމުގައި ދަންނަވަމެވެ.

މިކަމާ ގުޅޭ އިތުރު މައުލޫމާތު ފުޑް އެންޑް ޑްރަގް އޮތޯރިޓީގެ ފުޑް ސޭފްޓީ ޑިވިޜަނަށް ގުޅައިގެން ލިބެން ހުންނާނެއެވެ. އަދި މި އިއުލާނާއި ގުޅޭ އިތުރު މައުލޫމާތު މިނިސްޓްރީގެ ވެބްސައިޓް www.health.gov.mv އިން ލިބެން ހުންނާނެއެވެ.

13 ނޮވެމްބަރު 2013

INFOSAN
COMMUNITY WEBSITE

INFOSAN Alert

INFOSAN Alert - Outbreak of Acute Hepatitis Potentially Associated With Dietary Supplement Products Labeled OxyElite Pro

Date: November 1, 2013
Countries: United States of America
WHO regions: Region of the Americas

Hazard: Toxin/Chemical › Unknown

Food involved: Dietary supplement for energy boost body building and weight loss
Illness reported: Yes
Number of ill people: 56
Reported to IHR: Yes

Alert details:
Acute Hepatitis Illnesses Potentially Associated With Dietary Supplement Products Labeled OxyElite Pro

The U.S. Food and Drug Administration (FDA), the Center for Disease Control and Prevention (CDC), and state and local officials are investigating a number of hepatitis illnesses potentially associated with the use of a dietary supplement labeled as OxyElite Pro.

As of 10/31/13, there have been 56 cases of acute non-viral hepatitis with an unknown cause subsequent to the use of a weight loss or muscle building dietary supplement identified nationally, with most of them being in the State of Hawaii. Forty-seven used the dietary supplement products labeled as OxyElite Pro during the 60 days prior to illness. At least 22 cases have been hospitalized with acute hepatitis; two cases have received liver transplants, and one person has died. CDC is also looking at other cases of liver injury nationwide that may be related.

On October 11, 2013, FDA issued a warning letter to USP Labs LLC in Texas (manufacturer of Oxy Elite Pro and VERSA-1) informing them that these dietary supplements are deemed to be adulterated due to the use of a new dietary ingredient (aegeline) that wasn't notified to the agency. Failure to immediately cease distribution of these products may result in enforcement action by the FDA. The agency is unaware of history of use or other evidence of safety of aegeline when used in these products. The Warning Letter is available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm371203.htm#.

It has not yet been determined whether there is a connection between the use of dietary supplements containing aegeline and liver illness. Laboratory analysis of the product to date has not identified a causal etiologic agent, and more specific testing is ongoing. FDA is analyzing the composition of product samples that have been collected from many of the cases.

FDA has advised consumers to discontinue using any dietary supplement products labeled as Oxy Elite Pro and VERSA-1 while the investigation continues. OxyElite Pro and VERSA-1 are sold nationwide through a wide range of distribution channels, including the internet and retail stores that sell dietary supplements. These products are marketed for energy boost, body building, and weight loss. Currently we do not have any information on international distribution. As additional information becomes available regarding this investigation, including distribution information, it will be disseminated.

For more information, see FDA's website: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm370849.htm

Attached is an article published in "Morbidity and Mortality Weekly Report" of the US Center for Disease Control on the investigation.

The Infosan Secretariat would like to receive information about cases of acute hepatitis which could be linked to this event or any information about the distribrion of the incriminated products outside of the United States of America. Since this product may have been distributed widely through the internet, it would be important to inform the public accordingly.

Link to document: Article in "Morbidity and Mortality Weekly Report" of the US Center for Disease Control on the investigation into tan outbreak of acute hepatitis potentially associated with dietary supplements labeled OXYElite Pro.

DISCUSS THIS! PRINTER-FRIENDLY VERSION


NSC 0-9492216307-3
PHARMACIST FORMULATED
USPlabs
OxyELITE Pro
Super Thermogenic™†
University Studied
OxyELITE Pro is Pharmacist-formulated & must be used with extreme caution, only by healthy adults capable of handling its true power. It is mandatory that users get clearance from their physician before use.†
DIETARY SUPPLEMENT
90 Capsules


OxyELITE Pro
POWDER
Plus Advanced Carnitine Transport System


Rx3-P12-158
30 Day Cycle
VERSA-1
MUSCLE | MIND BREAKTHROUGH
NEW Patent Pending Anabolic
VERSA-1: the first of its kind. Take your training to new levels and feel the unique power of this NEW patent pending breakthrough.
DIETARY SUPPLEMENT
30 Capsules