Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 9, 2013

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

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

SUBJECT: USP Labs LLC. Health Advisory [Drug]

AFFECTED PRODUCT: **Products labeled as OxyElite Pro**

Health Advisory; USP labs LLC of Dallas, Texas, and is sold nation-wide through a wide range of distribution channels, including the internet and retail stores that sell dietary supplements. USP labs LLC has informed the FDA that it will voluntarily cease distributing OxyElite Pro as the company cooperates with the investigation.

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail.**
The FDA advises consumers to stop using any dietary supplement products labeled as OxyElite Pro while the investigation continues. OxyElite Pro is sold nation-wide through a wide range of distribution channels, including the internet and retail stores that sell dietary supplements. Furthermore, the company believes that counterfeit versions exist, and that they may be implicated in the illnesses. Be aware that these counterfeit versions may be available for sale. If any of these products are found please contact this office at 317-233-3213.

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News Release

FDA Investigates Acute Hepatitis Illnesses Potentially Linked to Products Labeled OxyElite Pro

What is the Problem and What is Being Done About It?

The U.S. Food and Drug Administration (FDA) along with the Centers for Disease Control and Prevention (CDC) and the Hawaii Department of Health (DOH) are investigating a growing number of reports of acute non-viral hepatitis in Hawaii. There have been 29 cases of acute non-viral hepatitis with an unknown cause identified in the state. The Hawaii DOH has reported that 24 of these cases share a common link to a dietary supplement product labeled as OxyElite Pro.

Eleven of the 29 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. The FDA advises consumers to stop using any dietary supplement products labeled as OxyElite Pro while the investigation continues. OxyElite Pro is distributed by USP labs LLC of Dallas, Texas, and is sold nation-wide through a wide range of distribution channels, including the internet and retail stores that sell dietary supplements. USP labs LLC has informed the FDA that it will voluntarily cease distributing OxyElite Pro as the company cooperates with the investigation. The epidemiological investigation is being conducted by the Hawaii DOH and the CDC. As part of FDA's associated investigation, the agency is reviewing the medical records and histories of patients identified by the Hawaii DOH. The FDA is also analyzing the composition of product samples that have been collected from some of these patients. Additionally, the FDA is inspecting the facilities involved in manufacturing the product and reviewing production and product distribution records. Because USPlabs LLC has informed FDA that it believes counterfeit versions of OxyElite Pro are being marketed in the US and have been on the US market for some time, FDA is also investigating whether counterfeit product is related to any of the cases of acute hepatitis. In the interest of protecting public health, we are moving quickly to learn as much as possible. We recognize that people will be concerned about these illnesses, and we will provide updates as the investigation develops.

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