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

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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 USPlabs 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. USPlabs 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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What are the symptoms of acute hepatitis?

Symptoms of all types of hepatitis are similar and can include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay or gray-colored bowel movements, joint pain, yellow eyes, and jaundice.

What do Consumers Need to Do?

The FDA advises consumers to stop using any dietary supplement product labeled as OxyElite Pro while the investigation continues. OxyElite Pro is distributed by USPlabs 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.

Who should be Contacted?

Consumers who believe they have been harmed by using a dietary supplement should contact their health care practitioner.

If you think you have suffered a serious harmful effect or illness from a dietary supplement, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or [report online](#). The [MedWatch program](#) allows health care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices, medical foods and dietary supplements. The identity of the patient is kept confidential..

Consumers may also report an adverse event or illness they believe to be related to the use of a dietary supplement by calling FDA at 1-800-FDA-1088 or [online](#). FDA would like to know when a product may be related to a medical problem even if you are unsure the product caused the problem or even if you do not visit a doctor or clinic.

The information in this release reflects the FDA's best efforts to communicate what it has learned from the manufacturer and the state and local public health agencies involved in the investigation. The agency will update this page as more information becomes available.

For more information:

- [FDA: FDA Investigates Acute Hepatitis Illnesses Potentially Linked to OxyElite Pro](#)
- [FDA: Dietary Supplements – Adverse Event Reporting](#)

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