On October 8, 2013 the FDA reported that it was investigating multiple incidences of acute non-viral hepatitis in the state of Hawaii. The Centers for Disease Control and Prevention and the Hawaii Department of Health are involved with this investigation as well. Twenty-nine cases of non-viral hepatitis have been reported with an unknown cause. Twenty-four of these events share a common association with OxyElite Pro, a dietary supplement distributed by USPlabs LLC in Dallas, Texas. This dietary supplement is marketed as a fat burner and is nationally available at many retail stores and on the internet. At this point in time, 11 people have been hospitalized with acute hepatitis in Hawaii; two people underwent liver transplantation, and one died. In their investigation the FDA is reviewing medical records and histories of the affected patients and examining product samples that were collected from these patients. The agency is also inspecting manufacturing facilities and studying production and distribution records. USPlabs has informed the FDA that they suspect counterfeit OxyElite Pro is being produced in the United States; the FDA is investigating this possibility as well. The CDC is assessing other liver injury events in the United States that could be connected. The FDA recommends that consumers do not use any dietary supplements labeled as OxyElite Pro while this investigation is underway.

Non-viral hepatitis is inflammation of the liver and can be classified as toxic or drug-induced (idiosyncratic). Although most people fully recover from this disorder, it is possible to develop fulminating hepatitis or cirrhosis. Hepatitis symptoms include: fever, fatigue, appetite loss, nausea, vomiting, abdominal pain, dark urine, gray-colored stool, joint pain, pruritis, and jaundice. Patients who suspect they have experienced harm from this supplement should contact their health care provider. The FDA encourages health care professionals and patients to report adverse events from OxyElite Pro at www.fda.gov/MedWatch/report.htm.

References:


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