FDA Investigation Summary: Acute Hepatitis Illnesses Linked to Certain OxyElite Pro Products

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What was the Problem and What was Done About It?

In 2013, the U. S. Food and Drug Administration (FDA), along with the Centers for Disease Control Prevention (CDC), the U.S. Department of Defense (DoD) Armed Forces Health Surveillance Center, and state and local health officials, investigated an outbreak of acute non-viral hepatitis that began in Hawaii.

According to CDC, 97 persons with acute non-viral hepatitis were identified in this outbreak, 72 of whom had reported exposure to an OxyElite Pro branded product. Of these cases, at least 47 were hospitalized, at least 3 received a liver transplant, and one death was reported. The estimated illness onset dates ranged from April 10, 2013 to October 24, 2013.

On October 11, 2013, the FDA issued a warning letter to USPlabs LLC of Dallas, Texas, informing the company that the dietary supplements OxyElite Pro and VERSA-1 were adulterated, and that failure to immediately cease distribution of these products could result in enforcement action.

The warning letter stated that the products were deemed to be adulterated because they contained aegeline, a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) that was not the subject of a required notification to FDA.

Specifically, USPlabs failed to provide the FDA with evidence, as required by law, that aegeline, also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide, was reasonably expected to be safe for use in its dietary supplements.

In a letter dated Nov. 6, 2013, the FDA notified USPlabs about findings indicating a link between the use of certain OxyElite Pro products and a cluster of liver illnesses reported in Hawaii. The letter also noted that cases of liver damage after use of these OxyElite Pro products had been found in a number of other states.

The letter summarized the results of FDA's review of 46 medical records of cases from the outbreak. The reviewed records indicated that 27 of the 46 patients, or 58 percent, had taken a dietary supplement labeled as OxyElite Pro prior to becoming ill. Seventeen of these 27 patients (or 63 percent) reported that OxyElite Pro was the only dietary supplement they were taking. One death had occurred among these patients, another patient had required a liver transplant, and others were awaiting liver transplants. Based on review of the medical records and other evidence obtained in FDA's investigation, the letter concluded that there was a reasonable probability that the OxyElite Pro dietary supplements listed in the letter were adulterated and that use or exposure to the dietary supplements would cause serious adverse health consequences or death to humans.

The letter also notified USPlabs that if the company did not initiate a voluntary recall, the FDA could by law order the company to immediately stop distributing the dietary supplements and immediately notify other parties to stop distributing the dietary supplements. This action marked the second time the FDA had exercised its authority under the mandatory recall provisions of the FDA Food Safety Modernization Act.

On November 9, 2013, **USPlabs LLC, of Dallas, Texas, recalled the OxyElite Pro (ssLINK/UCM374394)** dietary supplement products that were the subject of FDA's Nov. 6, 2013 letter, and on November 19, 2013, **USPlabs expanded the recall (ssLINK/UCM375740)** to include another flavor of one of the products.

Additional information for consumers

- FDA: **USPlabs LLC recalls OxyElite Pro dietary supplements; products linked to liver illnesses (ssLINK/UCM374395)**

Additional information for industry

- FDA: **Dietary Supplements – Adverse Event Reporting (/Food/DietarySupplements/ReportAdverseEvent/default.htm)**
- FDA: **New Dietary Ingredient Notification Process (/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm)**

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.

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