OxyElite Pro Supplements RECALLED

Following actions by the Food and Drug Administration (FDA), a Texas-based company has agreed to recall and destroy a dietary supplement linked to dozens of cases of acute liver failure and hepatitis, including one death and illnesses so severe that several patients required liver transplants.

In addition to the recall of certain OxyElite Pro products, USPLabs assured FDA officials that it will destroy warehouse stocks of the supplement, with a retail value of about $22 million. FDA will oversee the destruction of the product.

"As soon as we suspected a possible link between OxyElite Pro products and cases of liver failure and non-viral hepatitis in Hawaii, we warned the public and immediately launched an investigation with state officials and the Centers for Disease Control and Prevention (CDC)," said Daniel Fabricant, Ph.D., director of FDA's Division of Dietary Supplement Programs. "Our mandate to protect the public was fulfilled by ensuring the swift removal of the product from the marketplace."

FDA used new enforcement tools provided by the FDA Food Safety Modernization Act to act quickly in the face of a potential danger to public health.

The supplement was advertised as an aid to losing weight and building muscles. FDA warned the company on Oct. 11, 2013, that certain OxyElite Pro products and another supplement, VERSA-1, are considered

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adulterated because they contain a new dietary ingredient, aegeline, for which the company did not provide evidence of safety.

While FDA's investigation is still ongoing, the agency continues to warn consumers to avoid using OxyElite Pro and VERSA-1.

Earlier this year, a stockpile of another formulation of OxyElite Pro was destroyed after being held through an FDA administrative detention order. A stimulant included in those products, DMAA, or dimethylamylamine, can cause high blood pressure and lead to heart attacks, seizures, psychiatric disorders and death.

After removing DMAA from its products, USPLabs substituted aegeline, among other ingredients, in certain OxyElite Pro products. Non-synthetic aegeline is an alkaloid extract from leaves of the Asian bael tree (Agele marmelos).

"Twice in a short period, this company has added new dietary ingredients to supplements without notifying the FDA and providing a reasonable expectation of safety, as required by law," said Fabricant. "Losses to the company should also serve as a reminder that FDA's laws and regulations serve a purpose and must be followed."

Evidence of Danger

On Sept. 13, 2013, FDA learned of a cluster of seven Hawaii residents with acute liver failure/non-viral hepatitis.

A joint investigation by the Hawaii Department of Health and CDC revealed that the patients all had consumed OxyElite Pro products. FDA meanwhile identified patients outside of Hawaii with similar liver dysfunction after using OxyElite Pro.

The FDA urged the public to avoid using products labeled as OxyElite Pro or VERSA-1 while the agency investigated further.

On Oct. 11, 2013, FDA warned the company that certain OxyElite Pro and VERSA-1 products were deemed adulterated and that failure to immediately cease distribution of both products could lead to enforcement actions. The FDA also outlined its findings of harm linked to OxyElite Pro.

As of the end of October 2013, there were 56 cases of acute liver failure or acute hepatitis linked to OxyPro Elite, 43 of them in Hawaii. The investigation continues.

Following the Law

While manufacturers of dietary supplements are not required to provide proof of safety and effectiveness prior to marketing, they are required to notify the FDA of plans to include a new dietary ingredient. They are also required to submit evidence that the dietary ingredient would reasonably be expected to be safe under the conditions of use recommended or suggested in the supplement labeling. A new dietary ingredient is defined as one not marketed in the United States before Oct. 15, 1994..

Companies are required to provide evidence of safety of the new dietary ingredient 75 days before the product goes to market. This notification was not made by USPLabs before it began using DMAA, a new dietary ingredient, in OxyElite Pro. FDA was likewise not informed when the company, no longer formulating with DMAA, began using the new dietary ingredient aegeline.

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"The new law provided us new tools to act when a potential hazard is introduced to the market," said Fabricant. "The goal, however, is to prevent these things from happening. Companies must realize there are consequences for their actions, and consumers can help by exercising caution." FDA

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