Charges filed against makers of nutritional supplements

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One company in nationwide sweep sold products with ingredient that caused liver damage, FDA says.

(HealthDay)—Criminal charges and civil injunctions have been filed against 117 makers and/or distributors of potentially dangerous dietary supplements, U.S. government agencies announced Tuesday.

One of the targets of the investigation—conducted by the U.S. Food and Drug Administration, the Department of Justice and other federal agencies—was USPlabs LLC of Dallas, which sold popular workout and weight loss supplements.

The government says USPlabs and its executives claimed to use natural plant extracts in products called Jack3d and OxyElite Pro. However, they actually used a synthetic stimulant made in a Chinese chemical factory and knew of studies that linked these products to liver toxicity, the

government said.

In October 2013, USPlabs said it would stop distribution of OxyElite Pro because it had been linked to an outbreak of liver damage. However, the company then tried to sell as much of the product as quickly as possible at dietary supplement stores nationwide, according to an FDA news release.

"The criminal charges against USPlabs should serve as notice to industry that if products are a threat to public health, the FDA will exercise its full authority under the law to protect Americans and bring justice," Howard Sklamberg, FDA deputy commissioner for global regulatory operations and policy, said in the news release.

The chemical in the USPlabs products is aegeline, a synthetic version of a chemical found in a tree that grows in parts of Asia. Liver damage in some people who used the products was so severe that they required liver transplants, and one person died, the FDA said.

The USPlabs defendants were arrested or surrendered to the U.S. Marshals Service on Tuesday, and federal agents seized assets in dozens of investment accounts, real estate and other items.

As part of the investigation, another complaint was filed in federal court against Bethel Nutritional Consulting Inc., along with the company's president and vice president. The complaint alleges Bethel and its executives distributed tainted and misbranded dietary supplements and unapproved new drugs nationwide, federal officials said.

Some of the products marketed by Bethel contained potentially harmful drugs, including sibutramine and lorcaserin, the FDA said. Sibutramine was the active ingredient in the obesity drug Meridia, which was removed from the U.S. market in 2010 due to the risk of heart attack

and stroke.

Lorcaserin is the active ingredient in the obesity drug Belviq, which was approved by the FDA in 2012. Lorcaserin can cause serious side effects, however, particularly when taken with certain depression and migraine medications, and may also cause attention or memory problems, the FDA said.

Within the last year, the FDA has issued warnings to consumers about more than 100 dietary supplements found to contain hidden active ingredients. Many of the products are marketed for weight loss, body building and sexual enhancement, the agency said.

Also over the last year, the agency has sent warning letters to companies selling dietary supplements that contain BMPEA and DMBA, two ingredients that do not meet the legal definition of a dietary ingredient.

Warning letters have also been sent to several companies selling pure powdered caffeine products that pose a risk of illness or injury to consumers, the FDA said.

More information: The U.S. Food and Drug Administration has more about dietary supplements.