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by Josh Long - © November 7, 2013

"Although the company knows of no valid concern about the safety of aegeline or OxyElite Pro, the company has made the business decision, in light of the adverse publicity, to reformulate the product and to discontinue the use of aegeline in the United States," USPlabs chief compliance officer Kenneth Miles wrote in the Nov. 4 letter (<http://www.documentcloud.org/documents/816053-usplabs-response-to-fda-warning-letter-nov-4-2013.html>), which *USA TODAY* publicized today while reporting on the development (<http://www.usatoday.com/story/news/nation/2013/11/06/usplabs-reformulating-oxyelite-pro-and-discontinuing-use-of-aegeline/3459235/>).

Hawaii officials are investigating 36 illnesses associated with OxyElite Pro, Sarah Park, M.D., State Epidemiologist with the Hawaii State Department of Health, said yesterday in an interview with **Natural Products INSIDER**. At least two illnesses required liver transplants and officials have reported one death.

"We don't feel that they [the other products] are part of the same investigation or the same cluster," she said.

CDC is reportedly aware of other cases in the mainland United States associated with OxyElite Pro. A spokesperson for the health agency told **INSIDER** CDC had confirmed 56 cases as of yesterday. She declined to provide further details, including the number of individuals who have been hospitalized.

The health agency excluded certain individuals from its definition including those people who suffered chronic alcohol use, preexisting autoimmune hepatitis, and such chronic liver diseases as hemochromatosis and Wilson's disease.

Park said Hawaii health officials cannot precisely identify the "actual issue about the product."

"For that, we rely on the FDA for their product testing and their product investigation," she said, although Hawaii officials have ruled out speculation that a bad batch of OxyElite Pro sickened people.

"From our perspective, there are different lot numbers" associated with the outbreak, Park said. "There is no central distribution point that only sends to Hawaii."

She explained the products originated from several distribution points in the mainland United States, and several customers purchased OxyElite Pro over the Internet.

FDA and Hawaii officials previously said victims of the outbreak were not predisposed to liver disease, increasing the likelihood that OxyElite was responsible for the illnesses. For instance, an FDA official, William Correll, told USPlabs in the Oct. 11 letter that several individuals were healthy before they fell ill.

"We specifically excluded anyone who had signs of infection especially infection that we know exposes you to hepatitis," Park added.

Whether aegeline contributed to the illnesses remains under investigation. But USPlabs denies the substance is unsafe.

According to Miles, aegeline was first isolated from the bael tree—a native of India—more than 60 years ago. He refuted FDA's contention that aegeline is a new dietary ingredient (NDI) that necessitated a notification to the agency because he said the substance has been present in the food supply and has not been chemically altered.

"Because aegeline is unquestionably a constituent of the fruit, leaves, and bark of the bael tree, all of which have been used as food for centuries, and aegeline can be extracted from these three parts of the bael tree without any chemical alteration, an NDI submission to FDA for aegeline is not required," Miles wrote in the letter to FDA. "As is true for the majority of dietary ingredients, most of the aegeline used in dietary supplements is a synthetic counterpart of the natural extract."

A spokesperson for FDA said the "investigation is ongoing" and the agency is presently reviewing USPlabs' response to the warning letter.

Meanwhile, Park acknowledged she would like to determine what actually caused the illnesses in Hawaii, but such conclusive findings may be elusive.

"Sometimes, the best I can do is find the strongest association," she said.

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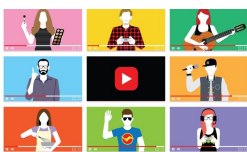


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