USPlabs agrees to cease operations under plea agreement

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Natural Products Insider Josh Long | Mar 14, 2019

It promised to be a high-stakes criminal trial involving the dietary supplement industry—with accusations of widespread fraud and questions over a distributor's role in a 2013 outbreak of hepatitis that led to hospitalizations, liver transplants and even one death.

But the federal government's case against USPlabs LLC and its co-defendants has been resolved through plea bargains and a diversion agreement.

USPlabs has agreed to cease its business activities within 90 days of entry of a plea agreement and immediately begin liquidating its inventory, according to its plea agreement filed Feb. 28, 2019, with the U.S. District Court for the Northern District of Texas. The parties also agreed USPlabs should be sentenced to two years of probation.

USPlabs President Jonathan Doyle, its CEO Jacobo (aka Jacob) Geissler and USPlabs each pleaded guilty to one count of conspiracy to introduce misbranded food into interstate commerce with intent to defraud and mislead.

"Americans who choose to take dietary supplements expect that those products are safe and properly labeled," FDA Commissioner Scott Gottlieb, M.D., said in a March 13 news release distributed by the U.S. Department of Justice (DOJ). "Dietary supplement labeling that falsely or misleadingly declares its contents presents a risk to the public, and the FDA will exercise its full authority under the law to bring to justice all those who produce and distribute misbranded dietary supplements."

As part of the conspiracy, "USPlabs ordered chemicals from Chinese chemical sellers as prospective and actual ingredients for use in dietary supplements, and instructed and agreed to have those powders labeled falsely as food substances," according to the superseding 11-count grand jury indictment filed in 2016.

On March 13, two of the seven co-defendants pleaded guilty to introducing misbranded food into interstate commerce with the intent to defraud or mislead before U.S. District Judge Sam A. Lindsay: Matthew Hebert and Cyril Willson, Erin Dooley, a spokeswoman with the U.S. Attorney's Office in Texas, confirmed via email.

Hebert and Willson are scheduled to be sentenced July 8, and according to federal prosecutors, they each face up to three years in prison.

“Consumers deserve to know exactly what’s in their dietary supplements,” said Erin Nealy Cox, U.S. Attorney for the Northern District of Texas, in a statement. “We cannot stand by as supplement companies deceive customers—especially when they use untested, suspect ingredients in their products.”

Hebert oversaw product packaging design for USPlabs, while Willson coordinated USPlabs’ scientific research and identified new substances as prospective ingredients in products, according to the indictment.

S.K. Laboratories Inc., which manufactured supplements for USPlabs, pleaded guilty to one count of introduction of misbranded food into interstate commerce. Sitesh Patel, vice president of S.K. Laboratories, pleaded guilty to one count of conspiracy to introduce misbranded food into interstate commerce with intent to defraud and mislead; and a separate count of introduction of misbranded food into interstate commerce.

In February, co-defendant Kenneth Miles entered into a one-year diversion agreement and the charges against him were dismissed, Dooley said. Miles was a quality assurance (QA) executive who oversaw compliance of USPlabs’ products with the Federal Food, Drug & Cosmetic Act (FDCA), the indictment stated. Pretrial diversion functions as alternative to prosecution and aims to divert individuals into a program of supervision and services that the U.S. Probation Service administers, according to the DOJ.

All the defendants who pleaded guilty to crimes are awaiting sentencing, and some of them could spend several years in a federal penitentiary. For example, the government recommended Doyle serve no more than 48 months in prison, although the judge overseeing the case—Lindsay—could impose a sentence of up to five years in prison for the criminal count, according to his plea agreement.

Geissler also could be sentenced to up to five years in prison.

Per the government’s recommendations, Patel could be sentenced on Aug. 12 to six years in prison. Patel already served time in prison after being convicted of conspiracy and mail fraud in an unrelated criminal case involving prohormones in dietary supplements.

The individuals named as defendants in the case, together with USPlabs and S.K. Laboratories, agreed to pay criminal fines and forfeitures totaling about $60 million, according to the DOJ.

USPlabs once was a thriving supplement distributor with hundreds of millions of dollars in sales of dietary supplements that contained a controversial compound known as DMAA (1,3-dimethylamylamine). But the grand jury indictment alleged the fraudulent behavior of USPlabs and its co-conspirators allowed them to make at least $400 million over a five-year period beginning in 2008.

Among their purported misdeeds: making false and misleading statements concerning the ingredients in their products, such as Cynanchum auriculatum root powder and DMAA, which

FDA describes on its website as an “amphetamine derivative” that may result in cardiovascular problems, such as shortness of breath, heart attack and seizures.

“Dietary supplement makers may not disregard the law and trick consumers about what is in their products,” Jody Hunt, assistant attorney general for DOJ’s Civil Division, said in a statement. “Consumers are entitled to trust that the products they consume are safe. We will continue to investigate and prosecute those who enable the sale of mislabeled and potentially unsafe dietary supplements.”

None of the lawyers representing the defendants immediately responded to requests for comment for this article.

State and federal authorities linked USPlabs’ supplement, OxyElite Pro, to a 2013 outbreak of liver injuries in Hawaii and the continental United States. At the time of the hepatitis outbreak linked to USPlabs, Daniel Fabricant, Ph.D., oversaw FDA’s Division of Dietary Supplement Programs. Under his leadership, the agency threatened to invoke its mandatory recall authority unless USPlabs removed OxyElite Pro supplements from the market that contained an ingredient known as aegeline.

But even after USPlabs promised the public and FDA that it would stop distribution of the product, the company “engaged in a surreptitious, all-hands-on-deck effort to sell as much OxyElite Pro as it could as quickly as possible and attempted to ship the rest of the OxyElite Pro in its possession out of the United States to avoid having FDA seize the product,” the indictment alleged.

“The story of USPlabs is one that went up like a rocket and crashed,” Fabricant, president and CEO of the Natural Products Association (NPA), reflected Thursday in a phone interview. “We’re still a country of laws, and the laws matter.”

He suggested the case against USPlabs shows FDA has the necessary tools to act when an entity regulated by the agency is endangering the public.

“When somebody puts people in harm’s way and uses the [Federal] Food, Drug & Cosmetic Act, there are consequences,” Fabricant concluded.