

Safety Concerns: Medicines

**SAFE
MEDS
ALERT**



Dietary Supplement Aimed at Weight-loss Recalled Due to Presence of Undeclared Sibutramine

October 17, 2018

This is a reprint of an FDA Alert.

Fat Burners Zone is voluntarily recalling 1 lot of Zero Xtreme, capsules to the consumer level. FDA analysis has found Zero Xtreme to be tainted with sibutramine. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market due to safety concerns. The presence of Sibutramine in Zero Xtreme renders it an unapproved drug for which safety and efficacy has not been established and, therefore, subject to recall.

Risk Statement: Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug approved by FDA for marketing in 1997 for prescription treatment of obesity and, subsequently, withdrawn from the U.S. market on December 21, 2010, after clinical data indicated Sibutramine poses an increased risk of heart attack and stroke.

[Click here to read the entire alert.](#)

FDA Contacts

For Adverse Events
[FDA Med Watch](#)

FDA's [Office of Criminal Investigations \(OCI\)](#)
800-551-3989

FDA FAX
800-332-0178

[Previous Alerts](#)



Learn more about [The Partnership for Safe Medicines](#) mission and share our resources.

Counterfeit Pills Made with Fentanyl in U.S. News

[Wyoming](#) has become the 45th state where counterfeit pills made with fentanyl have been found. The Gillette News Record reported the first publicly known instance of a counterfeit pill made with fentanyl poisoning a resident in Wyoming. Ethan Herrera and Makala Butz, both 21-years-old and from Worland, face felony charges for selling the counterfeit oxycodone pills that caused a non-fatal overdose in an area resident. An affidavit filed in court stated: "If not for the actions of family and first responders, (the victim) would most likely have died as a result of the overdose."

[Learn more about fentanyl pills in Wyoming.](#)

In [Texas](#), a suspect has been arrested in the death of 21-year-old Rice University football player on March 2, 2018 from the toxic effects of carfentanil caused by two counterfeit hydrocodone pills. Carfentanil is an analogue of fentanyl and is 10,000 times more potent than morphine and 100 times more potent than fentanyl,

[New Death Count Charge Announced Against Utah Man Who Allegedly Ran A Major Counterfeit Fentanyl Pill Ring](#)

A federal grand jury handed down a second superseding indictment against a Utah man that the U.S. Department of Justice (DOJ) contends was the leader of a drug ring that shipped hundreds of thousands of counterfeit pills, according to The Salt Lake Tribune. The previous indictments against Aaron Shamo charged him with a total of 12 counts. The new one added a new count of aiding and abetting the distribution of a controlled substance resulting in death. A court document identified the deceased as R.K. and said that they died on June 13, 2016.

Shamo allegedly ran an international drug trafficking organization that imported fentanyl and alprazolam powders from China. Pill presses were used by members of the conspiracy to turn those powders into counterfeit oxycodone and Xanax pills which were sold online. Prosecutors allege that this drug ring, which operated from at least July 8, 2015 until November 22, 2016, distributed more than fake 800,000 pills.

[Learn more about the Aaron Shamo counterfeit pill case.](#)



What counterfeit drug incidents happened in your state? Check our [State Resources page](#) to learn about counterfeit medication in your community.

according to the U.S. Drug Enforcement Administration. Police allege that the student purchased several of the fake pills from a former Rice Owl football player.

[Learn more about fake pills made with fentanyl and carfentanil in Texas.](#)

Three individuals have been arrested in [New York](#) for selling counterfeit pills made with fentanyl. A press release from the U.S. Drug Enforcement Administration (DEA) announced the arrest and the indictment of three individuals for allegedly conspiring to manufacture and distribute counterfeit pills containing fentanyl, heroin, and methamphetamine.

[Learn more about fentanyl pills in New York.](#)

[US FDA Joins Interpol And Other](#)

[International Enforcement Agencies For Operation Pangea XI](#)



The United States Food and Drug Administration (FDA) has announced the conclusion of Operation Pangea XI's International Week of Action. In its eleventh year, Operation Pangea targets websites that sell counterfeit

and misbranded drugs. This year's effort shut down 465 websites that were selling non-FDA approved prescription drugs including drugs for oncology, antivirals, opioids and other untested prescription drugs to U.S. consumers.

FDA Commissioner Scott Gottlieb, M.D. described Pangea's mission, "The sale of potentially dangerous and counterfeit drugs by criminal networks on the internet is a large and growing threat to the public health. The illegal online pharmacies that we're taking action against are often run by sophisticated criminal networks that knowingly and unlawfully distribute illicit drugs, including potentially counterfeit medicines and controlled substances both on the surface and dark web. Consumers go to these websites believing that they're buying safe and effective medications. But consumers are being put at risk by individuals who put financial gains above patient safety. I'm particularly concerned about the ease with which consumers can gain access to controlled substances and prescription opioids online. This is one reason why we've stepped up our efforts, both from a policy and enforcement standpoint, to take

these bad actors down."

[Read more about Operation Pangea XI.](#)