FDA Uses Authority To Remove Salmonella-Tainted Organic Kratom Products From Shelves

By ACSH Staff — April 3, 2018

It may not seem like the U.S. Food and Drug Administration has much interest in supplements, since by now they have gotten used to the 1994 Dietary Supplement Health and Education Act signed by President Bill Clinton, which basically gave an entire class of products exemption from oversight unless people were poisoned provided they wrote a disclaimer that their claims were not tested by FDA.

The new administration of FDA Commissioner Scott Gottlieb, M.D. has been much more proactive in protecting consumers from goods that have hid behind a political shield in the past, and that is why products containing the opiate kratom made by Triangle Pharmanaturals LLC have been pulled from shelves. Not because of the kratom, though FDA is understandably worried about that also, but because they contain salmonella.

The company refused to withdraw the products voluntarily and so the FDA, for the first time, used its authority under the Food Safety Modernization Act to issue a mandatory recall order to protect Americans from contaminated food products [1]. The FDA is advising consumers to discard the products that are part of the mandatory recall, which include, but are not limited to: Raw Form Organics Maeng Da Kratom Emerald Green, Raw Form Organics Maeng Da Kratom Ivory White, and Raw Form Organics Maeng Da Kratom Ruby Red. There may be more.

Kratom is the common name for the Mitragyna speciosa plant grown in Thailand, Malaysia, Indonesia and Papua New Guinea. Unlike most supplements, which are useless placebos, kratom actually is a drug [2] sold outside the FDA approval process. It contains psychoactive compounds mitragynine and 7-hydroxymitragynine [3] and it affects the same opioid brain receptors as morphine and appears to have properties that expose people who consume kratom to the risks of
addiction, abuse and dependence.

In this instance, two samples of kratom products manufactured by Triangle Pharmanaturals sold at Torched Illusions in Tigard, Oregon, which were collected by the Oregon Public Health Division, tested positive for salmonella, as did four additional samples of various types of kratom product associated with the firm collected by the FDA. FDA is also investigating a multi-state outbreak of salmonella infections linked to kratom products [4].

Recent concerns about opioid addiction have led supplement charlatans to claim kratom can help with addiction withdrawal but neither kratom nor its compounds have been proven safe and effective for any use and should not be used to treat any medical conditions.

“We continue to have serious concerns about the safety of any kratom-containing product and we are pursuing these concerns separately. But the action today is based on the risks posed by the contamination of this particular product with a potentially dangerous pathogen. Our first approach is to encourage voluntary compliance, but when we have a company like this one, which refuses to cooperate, is violating the law and is endangering consumers, we will pursue all avenues of enforcement under our authority,” said Gottlieb.