FDA In Brief: FDA objects to kratom compound intended for use as an alternative to prescription opioids and promoted with unproven claims to treat addiction

For Immediate Release: Feb. 26, 2018

Media Inquiries

FDA Office of Media Affairs (mailto:fdaoma@fda.hhs.gov)
301-796-4540 (tel:301-796-4540)

Company touted its kratom product's opioid characteristics, and made misleading statements about its compliance with FDA regulations

“Kratom is not a safe, benign plant. Data continues to provide strong evidence that kratom compounds are opioids with potential for addiction and abuse. At a time when we face an opioid epidemic of devastating proportions, manufacturers should not be allowed to mislead consumers into believing kratom products are a ‘safe’ alternative to prescription opioids or that kratom is effective therapy for opioid use disorder,” said FDA Commissioner Scott Gottlieb, M.D. “On the contrary, we have concerns that for some, kratom can become a gateway to continued addiction to opioids; or prevent some people from seeking safe and effective treatment for their addiction. Today, we notified a company making claims for a compound in kratom that its product is an unapproved new drug and an adulterated dietary supplement. The company is claiming that its product is a ‘natural substitute for opium,’ that it has ‘morphine-like effects,’ and that it can help relieve pain along with a litany of other ailments. Just as troubling, this company promotes kratom as effective in ‘curing addiction’ and treating ‘withdrawal symptoms.’ These unlawful practices not only mislead consumers, but can also prevent people suffering from addiction from seeking effective treatments. These claims are unproven and dangerous given the scientific evidence supporting kratom’s potential for abuse, addiction and serious health consequences, including death. We intend to take appropriate steps to protect the public health against kratom products that try to circumvent the law.”

Today, the U.S. Food and Drug Administration sent a letter (/media/111232/download) to a representative of Industrial Chemicals LLC, notifying the company that it has been making inaccurate and misleading statements about the legal status of its product,

Mitrasafe, which purports to be a 99 percent purity extract of mitragynine, one of the active compounds in kratom. The company's statements also establish that its product is intended to be used as a drug, even though the product has not gone through the required FDA approval process.

Examples of the many claims on Industrial Chemicals' website showing that Mitrasafe is intended for use as a drug include: it is a natural substitute for opium; it has morphine-like effects; it helps to treat withdrawal symptoms; it has analgesic properties; and it may provide pain relief. Neither kratom nor its compounds have been proven safe and effective for any use and should not be used to treat any medical conditions, nor should they be used as an alternative to prescription opioids or to treat opioid addiction. Before kratom or its compounds can be legally marketed for therapeutic uses in the U.S., its risks and benefits must be evaluated as part of the regulatory process for drugs established by Congress.

Additionally, the Mitrasafe website contains inaccurate and misleading statements about the legal status of Mitrasafe itself and dietary supplements containing Mitrasafe. Although the company complied with the requirement to submit a pre-market new dietary ingredient notification for Mitrasafe, the FDA advised the company in December 2016 that the agency believed the evidence relied on in the notification did not provide an adequate basis to conclude that Mitrasafe is reasonably expected to be safe and, in fact, raised safety concerns. For example, the toxicology evidence submitted showed adverse effects at all dose levels. In the absence of a history of use or other evidence sufficient to establish a reasonable expectation of safety, a new dietary ingredient is adulterated and may not be sold in the U.S. The company's assertion that it has complied with safety requirements for dietary supplements is not accurate.

The FDA recommends that consumers not purchase or use Mitrasafe or any kratom products and dispose (/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know) of any products currently in their possession. For individuals seeking treatment for opioid addiction, the FDA urges consumers to seek help from a health care professional. There are safe and effective, FDA-approved medical therapies available for the treatment of opioid addiction. Combined with psychosocial support, these treatments can be effective. There are three drugs (buprenorphine,

methadone and naltrexone) approved by the FDA for the treatment of opioid addiction, and the agency is committed to promoting more widespread innovation and access to these treatments to help those suffering from an opioid use disorder transition to lives of sobriety.

The FDA is taking new steps to support the process for developing additional safe and effective therapies for the treatment of opioid addiction. The agency will soon issue draft guidance that will make the development process for these products more efficient. We are also working with our partners across the Department of Health and Human Services to promote wider access to safe and effective treatments. There are also safe, non-opioid options available to treat pain. The FDA is fully committed to the development of, and access to, safe and effective treatments for patients suffering from addiction.

For more information:

- FDA and Kratom (/news-events/public-health-focus/fda-and-kratom)
- FDA Letter to Industrial Chemicals LLC and INI Botanicals Regarding Mitrasafe (mitragynine extract) (/media/111232/download)
- FDA oversees destruction and recall of kratom products; and reiterates its concerns on risks associated with this opioid (/news-events/press-announcements/fda-oversees-destruction-and-recall-kratom-products-and-reiterates-its-concerns-risks-associated)
- Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's scientific evidence on the presence of opioid compounds in kratom, underscoring its potential for abuse (/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-scientific-evidence-presence-opioid-compounds)

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and

medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.