



**AMERICAN KRATOM ASSOCIATION  
ISSUES OPEN LETTER TO US FOOD AND DRUG ADMINISTRATION**

**Requests an End to Attacks on  
Alternative Pain Management Therapies**

**FOR IMMEDIATE RELEASE**—February 27, 2018—Washington, DC

Dear Commissioner Gottlieb,

On November 1, 2017, the President’s Commission on Combating Drug Addiction and the Opioid Crisis issued a blistering rebuke of the Food and Drug Administration (FDA) and its failures to protect public health.

Despite rising numbers of overdoses and opioid-related fatalities, the FDA’s “inadequate oversight” failed to assure the safety, efficacy, and security of human drugs, significantly contributing to the opioid crisis in America today.

Citing nearly two decades of insufficient regulatory oversight on opioids, the Commission detailed the specific failures to protect public safety, even when overdose deaths mounted and when evidence of safe use of chronic consumers of opioids was substantially lacking.

Unfortunately, the FDA’s reaction to this criticism has been to unleash its regulatory powers on other alternative pain management therapies used by millions of Americans precisely to avoid dangerously addictive and deadly opioid medications.

Instead of addressing and overcoming the FDA’s failures in this regard, an increasingly hostile war has been waged against the following safe, non-addictive alternatives:

**Homeopathic Medicines:** Since 1988, the FDA has allowed the marketing and use of homeopathic medicines under the conditions set forth in the Compliance Policy Guide, Section 400.400, “Conditions Under Which Homeopathic Drugs May be Marketed.” On December 18, 2017, the FDA proposed a new, risk-based enforcement approach to homeopathic drug products that many believe is targeted specifically to pain management products that become very popular among those who use homeopathic medicines.

**Medical Foods:** On November 21, 2017, the FDA re-categorized a medical food used by thousands of patients suffering from osteoarthritis to control their chronic pain. This medical

food product had been recognized by the FDA for more than 13 years, but in the wake of the Commission's report, the FDA rescinded its recognition of Limbrel as a medical food and reclassified it as an unapproved new drug.

**Kratom:** The FDA announced a Public Safety Alert on kratom on November 14, 2017 claiming, incorrectly, that kratom was responsible for 36 deaths and that kratom has the same addiction and safety profile as opioids. The FDA continued its attack on kratom by increasing the number of deaths "associated with the use of kratom" and with further unsubstantiated claims that kratom is an "opioid" drug. Despite the fact that millions of Americans use kratom for relief of acute and chronic pain—and some use kratom as either a step-down from opioid abuse or as an alternative to dangerously addictive and potentially deadly opioid medications—the FDA is using all of its regulatory powers to remove kratom from consumer access in the United States.

Rather than accept (1) the documented deficiencies in fulfilling FDA regulatory responsibilities to protect the public health, and (2) to embrace the recommendations of the Commission to expand the use of non-opioid pain management therapies, the FDA has embarked on a crusade against all non-FDA approved alternative pain management therapies.

This will ultimately force patients to either acquire kratom and other alternative pain management therapies on the black market (where product quality is both suspect and potentially harmful), or to force consumers to the opioid prescription drug market. Several credentialed scientists have already predicted this will result in more opioid-related deaths in America.

If continued, the FDA's attacks on alternative pain management therapies will create a far more dangerous and potentially deadly pain management treatment environment. Patients seeking relief from acute or chronic pain have no desire to be forced into using opioid painkillers or become criminals as a result of the crusade against kratom.

On behalf of millions of kratom users safely using this natural botanical for their own health and well-being, end this attack on kratom and other alternative pain management therapies.

Sincerely,

Dave Herman  
Chairman, American Kratom Association