



Substance Abuse and Mental Health
Services Administration

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SEP 28 2018

TO: Elyse F. Greenwald, Substance Abuse and Mental Health Services Administration (SAMHSA) Office of Management and Budget (OMB) Desk Officer

FROM: Elinore F. McCance-Katz, Assistant Secretary for Mental Health and Substance Use

SUBJECT: Request for emergency clearance of a revision to the 2019 National Survey on Drug Use and Health (NSDUH) (OMB Control No. 0930-0110) to add two questions related to the drug kratom – **DECISION**

ISSUE

This memorandum requests emergency approval for a revision to the 2019 NSDUH (OMB Control No. 0930-0110) to add two questions related to the drug kratom. The two questions are as follows:

Q1. Have you **ever**, even once, used kratom?

- Yes
- No
- DK/REF

Q2. (If Q1 = Yes) How long has it been since you **last** used kratom?

- Within the past 30 days – that is, since [DATEFILL]
- More than 30 days ago but within the past 12 months
- More than 12 months ago
- DK/REF

In addition to the emergency approval, SAMHSA will complete the normal OMB review process and post the 60-Day and 30-Day *Federal Register* notices following the approval of the emergency data collection.

BACKGROUND

SAMHSA is seeking this emergency approval due to recent information concerning kratom's risk to public health and its impact on SAMHSA's ability to achieve our mission of increasing access to evidence-based substance use disorder treatment. This is especially concerning given the ongoing opioid crisis and its continued impact on American families.

Kratom is a tropical tree, native to Southeast Asia, with leaves that have psychotropic (mind-altering) effects. Kratom is generally regarded as an opioid given its known properties.

Countries, such as Malaysia and Thailand, in which the drug originated have banned its use because of its damaging and deadly effects. The Food and Drug Administration (FDA) used a Public Health Assessment via Structural Evaluation (PHASE) methodology to further elucidate the chemical properties of kratom. Based on their findings, FDA declared the compounds in Kratom, opioids.¹ Currently legal in the United States, kratom is easy to order on the internet, typically ingested as a leaf, pill or capsule. Two compounds in kratom leaves, *mitragynine* and *7- α -hydroxymitragynine*, interact with opioid receptors in the brain, producing sedation, pleasure, and decreased pain. Some users of kratom products reported becoming addicted to the drug.² There are reports that commercial forms of kratom have been laced with other compounds that have caused deaths. In the June 2018 issue of *Innovations in Clinical Neuroscience*, Bestha observed that products sold as kratom are being laced with compounds that have led to adverse effects such as seizures, psychosis and liver damage³. The FDA has been tracking deaths associated with kratom and kratom related products for the past several months.⁴

In the context of the opioid crisis, the FDA released a warning this month⁵ concerning unproven medical claims by companies marketing kratom. The FDA issued warning letters to two more vendors, Chillin Mix Kratom and Mitra Distributing, for marketing kratom products with scientifically unsubstantiated claims including to “relieve opium withdrawals” and to “treat a myriad of ailments including but not limited to: diarrhea, depression, diabetes, obesity, high blood pressure, stomach parasites, diverticulitis, anxiety, alcoholism, and opiate withdrawal.” These claims pose serious health risks to the American public. Specifically, such claims could keep people with opioid use disorder (OUD) from accessing FDA approved medication-assisted treatments (MAT) because people are relying on unsubstantiated claims rather than entering evidence-based treatments. People who do not get treatment are at greater risk for overdose and death. Any reliance on kratom products based on unsubstantiated claims may prevent people with OUD from entering evidence-based MAT and recovery.

Earlier this month, SAMHSA released the 2017 NSDUH survey data⁶ demonstrating a decrease in the misuse of prescription opioids in the past year and a significant decrease in the number of people initiating heroin use. While the overall use of prescription opioids has experienced a modest decline, the same cannot be said about heroin use, despite the apparent decrease in initiation over the past year – overall heroin use continues to climb over the last several years. It is critical that we understand whether kratom plays a role in the dangerous phenomenon of opioid use shifting, also known as drug substitution. Sethi et al. reported that kratom is now being used for a legal high in an online report in July of 2018 joining a chorus of other case reports supporting the same conclusion. This follows a report in late 2017 where Smith and Lawson reported that 64% of a sample of substance users enrolled in a residential treatment reported using kratom as a substitute for heroin and other non-prescription opioids⁷. The easy access issues associated with kratom are particularly concerning because there are no barriers to

¹ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm>

² NIDA. (2018, September 20). Kratom. Retrieved from <https://www.drugabuse.gov/publications/drugfacts>

³ Durga Bestha, “Kratom and the Opioid Crisis, *Innovation Clin Neurosc* 2018 Jun; 15(5-6): 11

⁴ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595622.htm>

⁵ <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620106.htm>

⁶ <https://www.samhsa.gov/data/sites/default/files/nsduh-ppt-09-2018.pdf>

use and as a result adverse consequences can happen. While heroin and prescription opioids require connections with the drug marketplace, it is possible to purchase kratom over the internet and at variety of retail outlets, thus it is more readily available, increasing the potential for substitution.

No nationally representative prevalence data is available on kratom use. Without national data on the use of kratom (e.g. who uses kratom, whether they use other drugs, the extent to which they have an opioid or other substance use disorder, whether they are seeking or receiving treatment, and extent of comorbidity), the federal government is unable to make data informed recommendations on prevention and treatment of substance abuse regarding this easily accessible, unregulated drug, in the midst of the opioid crisis.

The addition of these two questions to the 2019 NSDUH survey will have a de minimus effect on respondent burden while providing the government with vital public health data with which to make appropriate decisions. FDA continues to warn Americans to avoid kratom products and urges additional research is needed to better understand the use and risks of kratom. Understanding the prevalence of kratom use will allow further study as to the consequences of use.

The NSDUH is the most logical vehicle for these questions because of its large sample size and well established technical validity, and the extent to which answers to these two questions can be analyzed with important and relevant correlates that are collected in the rest of the NSDUH survey. Small samples and case studies are inadequate for legal and regulatory intervention. A general population survey will provide more robust and reliable information. Since it will be fielded in January 2019, we are not able to follow the normal OMB clearance procedure. The 2019 NSDUH survey will be finalized by October 25, 2018 in order to prepare for the data collection which begins by January 4th, 2019. Therefore, in order to be able to add these questions to the 2019 NSDUH survey, SAMHSA will need approval before October 25, 2018.

RECOMMENDATION

SAMHSA recommends OMB approve the addition of two kratom questions to the 2019 NSDUH Survey.



Elinore F. McCance-Katz, M.D., Ph.D.

DECISION

Approved: _____ Disapproved: _____ Need More Information: _____

SAMHSA OMB Desk Officer

Date