

# EXHIBIT 1



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

March 16, 2022

The Honorable Michael S. Lee  
United States Senate  
Washington, DC 20510

The Honorable Mark Pocan  
U.S. House of Representatives  
Washington, DC 20515

Dear Senator Lee and Representative Pocan:

Thank you for your letter about the substance *Mitragyna speciosa*, commonly known as kratom. As your letter notes, efforts to schedule kratom within the United States have not moved forward, and the World Health Organization (WHO) Expert Committee on Drug Dependence concluded that there was insufficient evidence to recommend a critical review of kratom. This means that WHO will take no further action to control kratom under the 1961 or 1971 Conventions at this time.

Your letter also noted that there is emerging science suggesting kratom may have therapeutic health benefits. The Department of Health and Human Services (HHS) is also aware of the emerging research and recent reports indicating that many individuals may be using kratom to self-treat serious health conditions, including, but not limited to, self-medication for managing pain, mental illness, and a substance use disorder. Additionally, there are reports that kratom is used for recreational purposes. Based on the Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health, it is estimated that over 2 million Americans 12 years and older used kratom in 2020. However, the prevalence of kratom use is difficult to estimate, and the reason for this prevalence remains unclear.

To that end, HHS and its component agencies are working to address knowledge gaps through research. Both the National Institutes of Health and the Food and Drug Administration (FDA) are supporting studies on the pharmacology of kratom's constituents, their toxicity and addictive liability, as well as their potential therapeutic benefits for pain and substance use disorder. While there are no FDA-approved uses for kratom, the Agency has a proven drug review process involving the evaluation of scientific research and data from rigorous controlled clinical trials to assess the risks and benefits of drugs. This includes a well-developed process for evaluating therapeutic uses of botanical drug products. FDA has also issued guidance on the proper

development of botanical drug products<sup>1</sup> and has a team of medical reviewers who can provide scientific expertise on botanical issues for researchers developing drugs made from plants.

To your final point regarding kratom safety and consumer protections, I agree with your concerns. Indeed, FDA continues to receive concerning reports describing safety concerns associated with kratom, including death. Many kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances.

While options for scheduling have been discussed, we believe that additional data and information are needed to understand the public health impact of kratom in terms of therapeutic benefits as well as safety risk. Discussions continue within HHS on mitigating actions to best address the various public health concerns presented, including potential unintended consequences that may arise from transitioning to riskier alternatives (for example fentanyl) if kratom were to be scheduled.

Thank you again for contacting me regarding this matter. Should you have further questions, please have your staff contact the Office of the Assistant Secretary for Legislation at (202) 690-7627

Sincerely,

A handwritten signature in blue ink, appearing to read "Xavier Becerra", is positioned above the printed name.

Xavier Becerra

Cc:

Hon. Linda Thomas-Greenfield, United States Ambassador to the United Nations

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<sup>1</sup> <https://www.fda.gov/files/drugs/published/Botanical-Drug-Development--Guidance-for-Industry.pdf>