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

December 20, 2021

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, the World Health Organization (WHO) Expert Committee on Drug Dependence (ECDD) has recently met to review kratom and six other substances. The outcomes from this meeting have not yet been announced by WHO. As required under the Controlled Substances Act (CSA), the Food and Drug Administration (FDA) published a Federal Register Notice (FRN) on July 23, 2021, inviting public comment concerning these substances, for the purpose of providing WHO with information from the United States, as requested by WHO of each member state. (86 FR 39038, Docket No. FDA-2021-N-0739). This FRN includes the WHO notification received by the Department of Health and Human Services (HHS) stating that kratom will be subject to a pre-review by the ECDD. The purpose of a pre-review is to determine whether current information justifies a critical review by the ECDD. A pre-review is a preliminary analysis, and therefore, the ECDD's findings at this stage should not determine whether the control status of a substance should be changed.

The ECDD is not expected to make recommendations to the UN Commission on Narcotic Drugs (CND) for the control of kratom at its next meeting in March 2022. Only if the ECDD recommends kratom for a Critical Review would WHO consider at a future meeting whether the information presented supports a recommendation for scheduling the substance under the 1961 or 1971 Conventions. Also, it should be noted that any recommendations by WHO for changes in the international control of a substance cannot go into effect under the treaties until affirmed by a vote of the voting members of the CND.

I understand that there is public interest in the use of kratom for therapeutic purposes but more research is needed to understand how kratom affects individual and public health. Compounds in kratom—mitragynine and 7-a-hydroxymitragynine—partially activate opioid receptors in the brain, leading to concerns that kratom could be addictive. The National Institutes of Health (NIH) is supporting studies on the pharmacology of kratom's constituents, their toxicity and

addictive liability, as well as their potential therapeutic benefits for substance use disorder and pain.

At the same time, HHS continues to have significant concerns about the use of kratom. To date, there are no FDA-approved uses for kratom, and FDA continues to receive concerning reports describing safety concerns associated with kratom, including death; notably, most kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances.

FDA has a proven drug review process involving the evaluation of scientific research and patient experience in rigorous controlled clinical trials to assess the risks and benefits of drugs. Furthermore, FDA has 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[1] and has a team of medical reviewers dedicated to providing scientific expertise on botanical issues for researchers developing drugs made from plants. Ultimately, FDA is responsible for ensuring that the benefits of approved drug products have been demonstrated and outweigh their risks when used as directed in approved labeling.

Thank you, again, for sharing your thoughts with me regarding this important matter. If you have further thoughts or questions, please have your staff contact the Office of the Assistant Secretary for Legislation at (202) 690-7627.

Sincerely,

Xavier Becerra

Cc:

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

[1] Botanical Drug Development: Guidance for Industry. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry