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FDA completes a kratom “dose finding study” on humans where no significant adverse events were observed even at very high doses.



The FDA acknowledged at a scientific meeting the data showed no significant safety concerns in the ascending dose study on kratom use and that clears the way for the planned Human Abuse Potential study.

The FDA announced on January 16, 2024, it will accept proposals to conduct a Human Abuse Potential (“HAP”) study to assess the potential severity of a kratom dependency or addiction liability. The HAP study is authorized only because the dose finding study showed kratom can be safely ingested.

An FDA scientist reported on some of the results of the dose finding study at the Third Annual Kratom Symposium on February 14-15, 2024. Researchers report that some of the policy staff at the FDA were “profoundly disappointed” at the lack of adverse events that occurred among human participants in the dose finding study, where the ascending doses got to 12 grams of kratom material before just 2 of the participants experienced some nausea. That level of kratom consumption is extraordinarily high among current kratom consumers.

It is reported that the scientists at FDA accepted the safety data for its evidentiary value and are now preparing to make a public presentation on the results of the dose finding study at a scientific conference in the fall of 2024.

That dose finding study data cleared the way for the HAP study to be advertised and that is expected to be completed within 2 years. It is important to note that the dose finding study had to demonstrate kratom can be safely consumed before the HAP study could ethically be advertised.

Kratom researchers are excited that the next level of studies on the safety and addiction liability of kratom extract products, and safe consumption levels can be identified, and the limits on kratom plant constituents in a kratom product before it is deemed to be adulterated. Those needed dose finding and HAP studies for kratom extract products will take several years after the current HAP study is completed.

i. <https://grants.gov/search-results-detail/351644>

ii. <https://pharmacy.ufl.edu/third-international-kratom-symposium/>

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