



## FDA Deputy Commissioner Signals Significant Shift in FDA Policy on Kratom and CBD Regulation.

*New regulatory approach exposes deep flaws in FDA's decades-long claims about kratom being dangerous as new FDA study finds "kratom appears to be well tolerated at all dose levels." (presented by FDA at scientific conference, February 2024)*



Kimberlee Trzeciak  
Deputy Commissioner  
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and International Affairs



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## WEBINAR

Major Highlights From Deputy Commissioner  
Trzeciak's Presentation

- **CBD and kratom are being marketed in almost every neighborhood you go into.**
- FDA has been **thinking about what the regulatory framework for these products should look like.**
- Based on what the **FDA knows about CBD, in particular, the Agency does not think that those products would be able to meet the safety standards currently in place for foods and dietary supplements today.**
- Given wide availability of both CBD and kratom, the **FDA wants to make sure consumers are educated on what they are taking and that adverse events are reported and minimized** – especially in children.
- The **FDA wants to work with Congress** on this effort, which includes how to ensure that CBD and kratom products are **clearly labeled with all ingredients**, and that these products are **not making their way into the hands of children,**
- **All adverse events need to be quickly and accurately reported** in such a way that the FDA can identify any trends.
- FDA wants to know **who is making the products containing kratom and CBD**, where they are being made, and that **they are manufactured or produced in a way that is safe.**
- This effort will take collaboration with the Hill and with stakeholders so the FDA can determine what regulations are needed to **ensure the safety of the products and the level of oversight that will be required.**