

Kratom Already Meets Definitions of Unlawful Products Under FD&C Law



How Kratom Is Evaluated Under Existing Law

WHAT ARE FD&C LAWS?

State FD&C laws mirror federal law and prohibit the sale of products that are:

- Adulterated (unsafe or contaminated)
- Misbranded (false or misleading claims)
- Unapproved drugs (marketed with drug-like effects without FDA approval)
- Harmful or deleterious

HOW KRATOM FITS THESE DEFINITIONS

Adulteration

Kratom has no established safe use and has been linked to contamination and safety concerns.

Misbranding

Often marketed with claims related to pain, mood, or withdrawal without approval

Unapproved Drugs

Acts on opioid receptors and produces drug-like effects without FDA approval

WHY THIS MATTERS UNDER STATE LAW

- FD&C laws already provide enforcement authority
- Products do not need scheduling to be removed from the market
- If a product meets these definitions, it may already be unlawful to sell
- States have independent authority to act regardless of federal scheduling

KEY QUESTION FOR POLICYMAKERS

If a product meets the definition of an unapproved drug and lacks proven safety, why is it still being sold?