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FDA Issues Warning Letters to Companies Illegally Selling Unapproved, Misbranded Kratom Products

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On June 25, FDA issued warning letters to two marketers and distributors of kratom products – Cali Botanicals and Kratom NC. FDA determined that the companies were illegally selling unapproved, misbranded kratom-containing drug products with unproven claims about their ability to treat or cure opioid addiction and withdrawal symptoms. Additionally, FDA found that the companies also made claims about treating pain, as well as other medical conditions like depression, anxiety, and cancer.

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In FDA's press release, Acting FDA Commissioner Ned Sharpless noted that there are no FDA-approved uses for kratom and the agency has been active in warning consumers about the serious risks associated with kratom. For example, as our readers may know, FDA has warned about both the high levels of heavy metals found in kratom products and the contamination of certain kratom products with salmonella. Indeed, FDA issued its first ever mandatory recall order for the salmonella-containing kratom products.

The June 25 warning letters allege that the companies used their websites and social media to illegally market kratom products and made unproven claims about the ability of the products to cure, treat, or prevent disease. Examples of the claims include:

- "Kratom acts as a μ-opioid receptor-like morphine."
- "In fact many people use kratom to overcome opiate addiction."
- "Of course, people who are using kratom to overcome a preexisting opiate addiction may need to use kratom daily to avoid opiate withdrawal."
- "Usage: It is for the management of chronic pain, as well as recreationally."

FDA reiterates that "[t]hese products have not been demonstrated to be safe or effective for any use and may keep some patients from seeking appropriate, FDA-approved therapies. Selling these unapproved products with claims that they can treat opioid addiction and withdrawal and other serious medical conditions is a violation of the Federal Food, Drug, and Cosmetic Act." FDA has requested responses from both companies within 15 working days.

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